# Hypnosis for pain management during labour and childbirth (Review)

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## TABLE OF CONTENTS

[Intervention Review]

# Hypnosis for pain management during labour and childbirth

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## ABSTRACT

### Background

This review is one in a series of Cochrane Reviews investigating pain management for childbirth. These reviews all contribute to an overview of systematic reviews of pain management for women in labour, and share a generic protocol. We examined the current evidence regarding the use of hypnosis for pain management during labour and childbirth. This review updates the findings regarding hypnosis from an earlier review of complementary and alternative therapies for pain management in labour into a stand-alone review.

### Objectives

To examine the effectiveness and safety of hypnosis for pain management during labour and childbirth.

### Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (11 January 2012) and the reference lists of primary studies and review articles.

### Selection criteria

Randomised controlled trials and quasi-randomised controlled trials comparing preparation for labour using hypnosis and/or use of hypnosis during labour, with or without concurrent use of pharmacological or non-pharmacological pain relief methods versus placebo, no treatment or any analgesic drug or technique.

### Data collection and analysis

Two assessors independently extracted data and assessed trial quality. Where possible we contacted study authors seeking additional information about data and methodology.

### Main results

We included seven trials randomising a total of 1213 women. All but one of the trials were at moderate to high risk of bias. Although six of the seven trials assessed antenatal hypnotherapy, there were considerable differences between these trials in timing and technique. One trial provided hypnotherapy during labour. No significant differences between women in the hypnosis group and those in the control group were found for the primary outcomes: use of pharmacological pain relief (average risk ratio (RR) 0.63, 95% confidence

interval (CI) 0.39 to 1.01, six studies, 1032 women), spontaneous vaginal birth (average RR 1.35, 95% CI 0.93 to 1.96, four studies, 472 women) or satisfaction with pain relief (RR 1.06, 95% CI 0.94 to 1.20, one study, 264 women). There was significant statistical heterogeneity in the data for use of pharmacological pain relief and spontaneous vaginal birth. The primary outcome of sense of coping with labour was reported in two studies as showing no beneficial effect (no usable data available for this review).

For secondary outcomes, no significant differences were identified between women in the hypnosis group and women in the control group for most outcomes where data were available. For example, there was no significant difference for satisfaction with the childbirth experience (average RR 1.36, 95% CI 0.52 to 3.59, two studies, 370 women), admissions to the neonatal intensive care unit (average RR 0.58, 95% CI 0.12 to 2.89, two studies, 347 women) or breastfeeding at discharge from hospital (RR 1.00, 95% CI 0.97 to 1.03, one study, 304 women). There was some evidence of benefits for women in the hypnosis group compared with the control group for pain intensity, length of labour and maternal hospital stay, although these findings were based on single studies with small numbers of women. Pain intensity was found to be lower for women in the hypnosis group than those in the control group in one trial of 60 women (mean difference (MD) -0.70, 95% CI -1.03 to -0.37). The same study found that the average length of labour from 5 cm dilation to birth (minutes) was significantly shorter for women in the hypnosis group (mean difference -165.20, 95% CI -223.53 to -106.87, one study, 60 women). Another study found that a smaller proportion of women in the hypnosis group stayed in hospital for more than two days after the birth compared with women in the control group (RR 0.11, 95% CI 0.02 to 0.83, one study, 42 women).

**Authors' conclusions**

There are still only a small number of studies assessing the use of hypnosis for labour and childbirth. Although the intervention shows some promise, further research is needed before recommendations can be made regarding its clinical usefulness for pain management in maternity care.

## PLAIN LANGUAGE SUMMARY

**Hypnosis for pain management during labour and childbirth**

Women's experiences of pain in labour are variable and complex but the intensity of pain can be made worse by fear, tension and anxiety. Techniques such as hypnosis have been proposed as ways to help deal with these fears and anxieties.

Hypnosis is an altered state of conscious awareness that involves, in part, a focus of attention to reduce awareness of the external environment. The increased responsiveness of individuals in hypnosis to communications, known as suggestions, can facilitate useful changes in perception and behaviour. Women can be guided into hypnosis by a practitioner during labour or individuals can learn self-hypnosis during pregnancy, for subsequent use during labour. This antenatal training is sometimes supplemented using an audio recording of hypnotic suggestions.

For childbirth, hypnosis is often used to focus attention on feelings of comfort or numbness as well as to enhance women's feelings of relaxation and sense of safety.

This review included studies on both practitioner-guided hypnosis and self-hypnosis techniques. We included seven trials that randomised 1213 women to hypnosis or to control groups receiving; standard childbirth preparation, usual care, a relaxation tape combined with relaxation practice in antenatal classes, supportive counselling or supportive psychotherapy. There were no significant differences between women in the hypnosis group and those in the control group in terms of additional use of drugs for pain management, the number of normal deliveries or women's satisfaction with the method of pain relief. Small, single trials reported that hypnosis reduced pain intensity, shortened the length of labour and reduced the number of women who stayed in hospital for more than two days after their baby was born compared with women who received relaxation training or supportive counselling. More evidence is needed to confirm these findings. In six trials the women were trained in self-hypnosis during pregnancy for later use during labour. In the other trial, the hypnotherapist was present during the woman's labour. All but one trial were at moderate or high risk of bias and only one study reported data on women who were approached to consider participating in the trial but chose not to participate.

Hypnosis may help relieve pain in labour but research so far conducted has not conclusively shown benefit.

## BACKGROUND

This review is one in a series of Cochrane Reviews examining pain management for childbirth. These reviews all contribute to an overview of systematic reviews of pain management for women in labour (Jones 2012), and share a generic protocol (Jones 2011).

### Description of the condition

Women's experiences of pain during labour are complex phenomena. Although almost all women report some pain during childbirth, their sensory and affective perceptions can vary widely (Lowe 2002). For example, some women describe the sensations of labour as more akin to extreme muscular exertion from physical activity, some as productive pain which signals that their baby's birth is closer, some compare it with intense period pain and others describe it as agony or like torture (Green 1998; Lundgren 1998; McCutcheon-Rosegg 1996). There have also been reports that occasionally women experience no labour pain and give birth unexpectedly (Gaskin 2003). A range of physiological and psychosocial factors have been identified, which may explain labour pain and its variability (Lowe 2002).

Traditionally, labour pain has been defined similarly to acute pain, "a complex constellation of unpleasant sensory, perceptual and emotional experiences and certain associated autonomic, physiologic, emotional and behavioural responses" (Bonica 1990a). However, unlike other acute pain, which can usually be attributed to pathologic processes, labour pain does not signal harm or pathology and is considered a normal part of birth (Lowe 2002). The physiological processes thought to cause pain during labour include uterine contractions dilating the cervix in the first stage of labour and the stretching of the vagina and pelvic floor as the baby descends during the second stage of labour (Bonica 1990b). Although pain intensity has been found to increase with frequency of contractions and greater cervical dilatation, these patterns are not consistent across women (Melzack 1984). Physical factors such as maternal positioning have also been found to affect pain, with women randomised to upright positions in the first stage of labour less likely to use epidural analgesia than women randomised to recumbent positions (Lawrence 2009).

Psychosocial factors including anxiety, fear, feelings of self-efficacy, coping skills and social support have also been shown to have a relationship with women's experiences of labour and labour pain (Hodnett 2011; Lowe 2002). For example, anxiety and fear of pain have been positively correlated with reported pain levels during labour (Lowe 2002). By contrast, women were less likely to use pain medications if they had a continuous support person for labour, and women's confidence in their ability to cope has also been associated with reduced pain perception (Hodnett 2011; Lowe 1989). Historically, Dick-Read 1947 made a influential theoretical contribution to the literature on psychological factors in labour. His cyclical "fear-tension-pain syndrome" linked women's feelings of fear and anxiety to muscular tension and pain in childbirth (Dick-Read 1947). In this model, high levels of maternal fear led to increased muscular tension, causing increased pain which in turn further heightened the woman's level of fear (Dick-Read 1947). This theory has been explicitly incorporated into a range of childbirth education programs, including the hypnosis-oriented program developed by Mongan 2005, and many antenatal education programs seek to reduce maternal anxiety and increase confidence.

The measurement of pain generally and the measurement of labour pain in particular is challenging given the subjective nature of the experience and the complex interpretations involved. Indeed, there is evidence that the way pain is measured can affect the way it is interpreted by individuals (Chooi 2011). Studies have also shown low levels of agreement between the subjective assessments of pain by patients and the estimates of medical staff (for example, Trentin 2001). Given these challenges, more objective measures such as use of pharmacological pain relief can be usefully supplemented with a range of subjective measures of pain experience.

### Description of the intervention

A wide range of methods for pain management are currently used by women during childbirth (Caton 2002). Commonly, these include pharmacological methods such as epidural analgesia and/or physical methods such as water immersion (Caton 2002). The use of psychological methods for comfort in childbirth has a very long history and concentrated forms of suggestion were reportedly used in Egyptian and Chinese societies (Bonica 1990b). The term 'hypnosis' was proposed by James Braid in the 1840s and it has been reported that the technique was soon adopted as a method of pain relief for childbirth (Platonov 1960).

There is considerable academic debate about whether hypnosis represents a distinct state of consciousness or whether it is a normal state, where social influence and cognitive-behavioural skills are used to enhance suggestibility (Gamsa 2003). However, the core components of hypnosis are generally described as involving reduced awareness of external stimuli, focused attention as well as increased absorption in and responsiveness to suggestions (Gamsa 2003). Suggestions are verbal and non-verbal communications used in order to achieve specific therapeutic goals (Cyna 2004). In the context of childbirth, suggestions may focus on increasing feelings of safety, relaxation and comfort, as well as potentially developing sensations of analgesia such as numbing.

There are two main methods for providing hypnosis interventions for childbirth: hypnotherapy delivered in-person by a practitioner; and self-hypnosis, where the practitioner teaches the mother how to induce a 'state of consciousness similar to meditation which results in failure of normally perceived experiences reaching conscious awareness' (Cyna 2004). Self-hypnosis can be taught to women individually or in groups, and can be supplemented with audio recordings for use at home. For example, in one US trial,

groups of 15 pregnant women had one-hour hospital-based training sessions each week for six weeks (Harmon 1990). The women were also given audio recordings of the hypnotic induction for daily practice leading up to the birth (Harmon 1990). The benefits of teaching women self-hypnosis before labour include the promotion of women's active participation and sense of control for managing anxiety and discomfort (Martin 2001). Alternatively, an example of hypnotherapy for childbirth guided by a practitioner was a trial in Philadelphia, where a trained medical student provided hypnosis to women in active labour in hospital (Rock 1969). This method of delivering the intervention was chosen as it was considered to be less time consuming than antenatal training and more predictable results were expected (Rock 1969).

## How the intervention might work

There is promising evidence that hypnosis may be effective in reducing acute pain across a range of settings, including burns treatment and other invasive medical procedures (Montgomery 2000; Patterson 2003). A meta-analysis of 18 studies of experimentally induced and clinical pain found that hypnotic analgesia provided a moderate to large analgesic effect for both types of pain (Montgomery 2000). Although most of the participants were reported to be randomly assigned to treatment or control conditions, most of the trials included in the analysis were small (Montgomery 2000) and there was no explicit assessment of potential sources of selection, attrition and selective reporting bias in the trials. Patterson 2003 also reported that several well-designed controlled trials supported the efficacy of hypnosis for acute pain in a large review of hypnosis and clinical pain. This review provided more detailed information about each trial, but again did not explicitly assess all potential sources of bias. A Cochrane Review of clinical hypnosis for acute pain in adults is planned which will include explicit assessment of potential biases (Hallquist 2007).

Neuro-imaging studies have provided evidence about the nature of neuro-physiological changes during hypnosis generally and during hypnotically-induced analgesia (Faymonville 2000; Maquet 1999). A positron emission tomography and magnetic resonance imaging study found hypnosis reduced pain experienced from hot, noxious stimuli and that the process was mediated by the anterior cingulate cortex (Faymonville 2000). Both the affective and sensory aspects of pain perception were reduced when participants used hypnosis (Faymonville 2000). Hypnosis has also been used to selectively alter the degree of unpleasantness of hot, noxious stimuli without changing the perceived intensity of the pain in a study designed to differentiate the cortical areas involved in the affective and sensory dimensions of pain (Rainville 1997).

In the context of pain management for childbirth, hypnosis is often considered alongside other non-pharmacological methods as focused on the affective aspects of the pain experience, such as reducing anxiety, fear, muscular tension as well as enhancing mood and increasing the woman's sense of control (Simkin 2004). However, there have been case reports of hypnosis used as the only analgesia for surgical procedures, including caesarean section, for highly hypnotisable individuals (for example, Kroger 1957).

Hypnotisability refers to the degree to which individuals follow suggestions during hypnosis and a number of scales have been constructed to measure and predict hypnotic suggestibility (Gamsa 2003). Some studies have found that highly hypnotisable individuals experienced greater pain relief than those who scored low on hypnotisability scales (Harmon 1990; Stam 1984), although other studies did not replicate this finding (Rock 1969; Samko 1975). Hypnotisablity may not be a stable characteristic with evidence that the ability to control pain can improve with repeated use of hypnoanalgesia (Lewis 1992) and that the physiological and hormonal changes associated with pregnancy may affect individuals' responsiveness to hypnosis (Alexander 2009). For example, a recent study found that women were significantly more hypnotisable when pregnant (Alexander 2009). This study used a repeated-measures design with 37 women and found a large, clinically meaningful effect ($d = 0.84$) for increased hypnotisability during pregnancy. Measured on the Creative Imagination Scale (CIS) (Barber 1979), which has a maximum score of 40, the women's mean CIS score when pregnant was 23.5 (standard deviation (SD) 6.9), compared with a mean CIS score of 18.7 (SD 6.6) when the women were between 14 and 28 months postpartum (Alexander 2009).

The safety of hypnosis for pregnant women was considered in an earlier systematic review (Cyna 2004). There were no reports of adverse effects attributed to the hypnosis intervention in the reviewed trials (Cyna 2004). However, two previously published reports of individual maternal mental disturbances, specifically antenatal psychotic symptoms and treatable postnatal anxiety and compulsive behaviour, were noted (Cyna 2004). The current review will also note any reports of adverse events.

## Why it is important to do this review

A range of pharmacological methods of pain management for labour exist; however, not all methods are routinely available across international maternity care settings. Some methods, such as parenteral opioids and epidural, have also been associated with increased risks of adverse maternal effects and increased rates of other medical intervention (Anim-Somuah 2011; Ullman 2010). The Australian and New Zealand College of Anaesthetists recommends consideration of non-pharmacological options before pharmacological options for pregnant women as pain medications generally cross the placenta (McIntyre 2010). Hypnosis has been recognised by organisations including the British Medical Association, the American Medical Association and the British Psychological Society as an effective clinical tool (AMA Council on Mental Health 1958; BMA Working Party 1955; BPS Working Party 2001). Like other non-pharmacological methods of pain management for childbirth, hypnosis can be used autonomously by women in

labour and may enhance feelings of self-confidence, mastery and well-being (Simkin 2004).There is also interest among expectant parents about the use of hypnosis for childbirth and at least two programs are widely available for community-based preparation in high-income countries (Howell 2009; Mongan 2005).

An earlier Cochrane review of complementary and alternative therapies for pain management in labour found that women taught self-hypnosis used less pharmacological analgesia and were more satisfied with pain management in labour than women randomised to control conditions (Smith 2006). The authors concluded that hypnosis may be beneficial as a method of pain management in labour but noted that only a small number of women had been studied (Smith 2006). This review provides the opportunity to separate hypnosis into a standalone review and update it with results from recently completed trials of hypnosis for pain management in childbirth.

# OBJECTIVES

To assess the effectiveness and safety of hypnosis for pain management during labour and childbirth.

# METHODS

## Criteria for considering studies for this review

### Types of studies

Randomised controlled trials (RCTs) and quasi-randomised controlled trials.

### Types of participants

Pregnant women. (This included women in high-risk groups, e.g. preterm labour or following induction of labour. We planned to use subgroup analysis to assess any possible differences in the effects of hypnosis for these groups where data were available.)

### Types of interventions

Preparation for labour using hypnosis and/or use of hypnosis during labour, with or without concurrent use of pharmacological or non-pharmacological pain relief methods versus placebo, no treatment or any analgesic drug or technique.

This review is one in a series of Cochrane reviews examining pain management in labour. These reviews contribute to an overview of systematic reviews of interventions for pain management in labour (Jones 2012), and share a generic protocol (Jones 2011). The current list is as follows:

1. Placebo/no treatment
2. Hypnosis (this review)
3. Biofeedback (Barragán 2011)
4. Intracutaneous or subcutaneous sterile water injection (Derry 2012)
5. Immersion in water (Cluett 2009)
6. Aromatherapy (Smith 2011a)
7. Relaxation techniques (yoga, music, audio) (Smith 2011c)
8. Acupuncture or acupressure (Smith 2011b)
9. Massage, reflexology and other manual methods (Smith 2012)
10. Transcutaneous electrical nerve stimulation (TENS) (Dowswell 2009)
11. Inhaled analgesia (Klomp 2011)
12. Opioids (Ullman 2010)
13. Non-opioid drugs (Othman 2011)
14. Local anaesthetic nerve blocks (Novikova 2012)
15. Epidural (including combined spinal epidural) (Anim-Somuah 2011; Simmons 2007)

### Types of outcome measures

The protocol for this review was formulated prior to the development of the generic protocol (Jones 2011), the outcome measures include both outcomes that were originally planned as well as all outcomes specified in the generic protocol.

#### Primary outcomes

- Use of pharmacological pain relief or anaesthesia at any time during labour and childbirth (as defined by trialists)
- Satisfaction with pain relief (as defined by trialists)
- Sense of coping with labour (as defined by trialists)
- Spontaneous vaginal birth

#### Secondary outcomes

- Pain intensity (as defined by trialists)
- Maternal pain score as measured by visual analogue pain scores or verbal numerical rating scores
- Severe pain experienced during the birth (as defined by trialists), measured in labour or postnatally
- Sense of control in labour (as defined by trialists)
- Satisfaction with childbirth experience (as defined by trialists)
- Birth experience worse than expected
- Effect (negative) on mother/baby interaction
- Breastfeeding at discharge from hospital
- Assisted vaginal birth
- Caesarean section
- Admission to special care baby unit/neonatal intensive care unit (as defined by trialists)
- Apgar score less than seven at five minutes

- Poor infant outcomes at long-term follow-up (as defined by trialists)
- Cost (as defined by trialists)
- Use of epidural/neuroaxial block as additional analgesia
- Preterm birth
- Induction of labour
- Augmentation of labour with oxytocin
- Length of labour (as defined by trialists)
- Perineal trauma (defined as episiotomy and incidence of tear - greater than first degree)
- Primary postpartum haemorrhage (> 500 mL)
- Need for postpartum blood transfusion
- Postnatal depressive symptoms (as defined by trialists)
- Number of maternal days in hospital after the birth
- Number of neonatal days in hospital after the birth
- Any other incidences or adverse events, e.g. post-dural puncture headache; maternal/neonatal death; maternal mental disturbance

## Search methods for identification of studies

### Electronic searches

We contacted the Trials Search Co-ordinator to search the Cochrane Pregnancy and Childbirth Group's Trials Register (11 January 2012).

The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

1. monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE;
3. weekly searches of EMBASE;
4. handsearches of 30 journals and the proceedings of major conferences;
5. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Details of the search strategies for CENTRAL, MEDLINE and EMBASE, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the 'Specialized Register' section within the editorial information about the Cochrane Pregnancy and Childbirth Group.

Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Co-ordinator searches the register for each review using the topic list rather than keywords.

### Searching other resources

We searched the reference lists of all available primary studies and review articles and planned to contact the primary authors of known studies to seek other published or unpublished trials.

We did not apply any language restrictions.

## Data collection and analysis

We used the following methods when assessing the reports identified by the search.

### Selection of studies

One review author, Leanne Jones (LJ) and a research associate Mohammad Othman (MO) independently assessed for inclusion all the potential studies identified as a result of the electronic search. Disagreements were resolved through discussion. Another review author Kelly Madden (KM) checked these assessments. Following discussion between the authors it was decided to include quasi-randomised controlled trials so as to optimise reporting of the available evidence.

### Data extraction and management

Two assessors, KM and LJ or MO independently extracted the data using the form designed by the review group for this purpose. For each included trial we collected information regarding the setting, methods of the trial (as per assessment of risk of bias), the participants, the nature of the intervention, and data relating to the specified outcomes. MO, LJ and KM entered the data into Review Manager software (RevMan 2011) and review authors (LJ, KM and PM) checked the data extraction and data entry.

We attempted to contact the authors of several of the original reports for clarification where information was unclear.

### Assessment of risk of bias in included studies

Two assessors, KM and MO or LJ independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We resolved discrepancies by discussion between two authors (KM and LJ).

#### (1) Sequence generation (checking for possible selection bias)

We described for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.

We assessed the method as:

- low risk of bias (any truly random process, e.g. random number table; computer random number generator);
- high risk of bias (any non-random process, e.g. odd or even date of birth; hospital or clinic record number); or

- unclear risk of bias.

#### (2) Allocation concealment (checking for possible selection bias)

We described for each included study the method used to conceal the allocation to control or intervention groups prior to assignment and assessed whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.

We assessed the methods as:

- low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth); or
- unclear risk of bias.

#### (3.1) Blinding of participants and personnel (checking for possible performance bias)

We described for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We considered that studies were at low risk of bias if they were blinded, or if we judged that the lack of blinding was unlikely to affect the results. We planned to assess blinding separately for different outcomes or classes of outcomes.

We assessed the methods as:

- low, high or unclear risk of bias for participants;
- low, high or unclear risk of bias for personnel.

#### (3.2) Blinding of outcome assessment (checking for possible detection bias)

We described for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received. We planned to assess blinding separately for different outcomes or classes of outcomes.

- low, high or unclear risk of bias for outcome assessors.

#### (4) Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data)

We described for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported, the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported, or could be supplied by the trial authors, we planned to re-include missing data in our analyses. We assessed methods as:

- low risk of bias (e.g. where there were no missing data or where reasons for missing data were balanced across groups);
- high risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; 'as treated' analysis done with substantial departure of intervention received from that assigned at randomisation); or
- unclear risk of bias.

#### (5) Selective reporting bias (checking for reporting bias)

We described for each included study how we investigated the possibility of selective outcome reporting bias and what we found. We assessed the methods as:

- low risk of bias (where it was clear that all of the study's prespecified outcomes and all expected outcomes of interest to the review were reported);
- high risk of bias (where not all the study's prespecified outcomes were reported; one or more reported primary outcomes were not prespecified; outcomes of interest were reported incompletely and so could not be used; the study failed to include results of a key outcome that would have been expected to have been reported); or
- unclear risk of bias.

#### (6) Other sources of bias (checking for bias due to problems not covered in (1) to (5) above)

We described for each included study any important concerns we had about other possible sources of bias. For example, where there was a potential source of bias related to a specific study design or where a trial was stopped early due to some data-dependent process.

We assessed whether each study was free of other problems that could put it at risk of bias and categorise as:

- low risk of other bias;
- high risk of other bias; or
- unclear whether there was a risk of other bias.

#### (7) Overall risk of bias

We made explicit judgements about whether studies were at high risk of bias, according to the criteria given in the *Handbook* ( Higgins 2011). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we considered it was likely to impact on the findings. We explored the impact of the level of bias through undertaking sensitivity analyses, *see* Sensitivity analysis.

### Measures of treatment effect

#### Dichotomous data

For dichotomous data, we presented results as summary risk ratio with 95% confidence intervals.

#### Continuous data

For continuous data, we used the mean difference if outcomes were measured in the same way between trials. We planned to use the standardised mean difference to combine trials that measured the same outcome, but used different methods.

#### Ordinal data

For ordinal data measured on scales (e.g. pain measured on visual analogue scales), we planned to analyse as continuous data and express the intervention effect as a difference in means or standardised difference in means. For ordinal data (e.g. satisfaction with pain relief) measured on shorter ordinal scales (e.g. excellent, very good, good), we planned to analyse as dichotomous data by combining categories (e.g. excellent and very good) and express the intervention effect using risk ratios.

### Unit of analysis issues

#### Cluster-randomised trials

We had planned to include cluster-randomised trials in the analyses along with individually-randomised trials. We planned to adjust their sample sizes using the methods described in the *Handbook* (Higgins 2011) using an estimate of the intracluster correlation co-efficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. If we used ICCs from other sources, we planned to report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identified both cluster-randomised trials and individually-randomised trials, we planned to synthesise the relevant information. We considered it reasonable to combine the results from both if there was little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit was considered to be unlikely.

We also planned to acknowledge heterogeneity in the randomisation unit and perform a sensitivity analysis to investigate the effects of the randomisation unit.

### Dealing with missing data

For included studies, we noted levels of attrition. We planned to explore the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using Sensitivity analysis.

For all outcomes we carried out analyses, as far as possible, on an intention-to-treat basis, i.e. we attempted to include all participants randomised to each group in the analyses, and analysed all participants in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial was the number randomised minus any participants whose outcomes were known to be missing.

### Assessment of heterogeneity

We assessed statistical heterogeneity in each meta-analysis using the $T^2$, $I^2$ and $Chi^2$ statistics. We regarded heterogeneity as substantial if $I^2$ was greater than 30% and either $T^2$ was greater than zero, or there was a low P value (less than 0.10) in the $Chi^2$ test for heterogeneity.

### Assessment of reporting biases

If there were 10 or more studies in the meta-analysis, we planned to investigate reporting biases (such as publication bias) using funnel plots. We planned to assess funnel plot asymmetry visually, and use formal tests for funnel plot asymmetry. For continuous outcomes we planned to use the test proposed by Egger 1997, and for dichotomous outcomes we planned to use the test proposed by Harbord 2006. If asymmetry was detected in any of these tests or was suggested by a visual assessment, we planned to perform exploratory analyses to investigate it.

### Data synthesis

We carried out statistical analysis using the Review Manager software (RevMan 2011). We used fixed-effect meta-analysis for combining data where it was reasonable to assume that studies were estimating the same underlying treatment effect: i.e. where trials were examining the same intervention, and the trials' populations and methods were judged sufficiently similar. If there was clinical heterogeneity sufficient to expect that the underlying treatment effects differed between trials, or if substantial statistical heterogeneity was detected, we used random-effects meta-analysis to produce an overall summary, if an average treatment effect across trials was considered clinically meaningful. We treated the random-effects summary as the average range of possible treatment effects and discussed the clinical implications of treatment effects differing between trials. If the average treatment effect was not clinically meaningful, we did not combine trials.

Where we used random-effects analyses, we have presented the results as the average treatment effect with its 95% confidence interval, and the estimates of $T^2$ and $I^2$.

### Subgroup analysis and investigation of heterogeneity

We investigated substantial heterogeneity using subgroup analyses and sensitivity analyses. We considered whether an overall summary was meaningful, and if it was, used random-effects analysis to produce it.

We planned to carry out the following subgroup analyses.

1. Spontaneous labour versus induced labour.

2. Primiparous versus multiparous.
3. Term versus preterm birth.
4. Continuous support in labour versus no continuous support.
5. Trimester (first versus second versus third trimester; first and second trimester versus third trimester) at commencement of hypnosis sessions.
6. Number of hypnosis sessions (less than four versus four or more).
7. Method of hypnosis intervention delivery (one-to-one versus group classes, audio CD versus no audio CD, hypnosis preparation prior to labour versus practitioner assisted hypnosis in labour).
8. Maternal anxiety levels (high versus low).
9. Maternal hypnotisability (high versus low).

We restricted subgroup analysis to the primary outcomes.
We planned to assess differences between subgroups by interaction tests available in RevMan 2011.

### Sensitivity analysis

We carried out sensitivity analysis to explore the effect of trial quality for primary outcomes in the review. Where there was risk of bias associated with a particular aspect of study quality (e.g. inadequate allocation concealment), we explored this by sensitivity analyses.

# RESULTS

## Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of studies awaiting classification; Characteristics of ongoing studies.
*See* Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies.

### Results of the search

We identified a total of 12 reports (11 studies) from the search strategy. A total of seven studies reporting data on 1213 women were included in this review (*see* Characteristics of included studies); two studies are ongoing (*see* Characteristics of ongoing studies); one study is awaiting classification (*see* Characteristics of studies awaiting classification); and one study was excluded (*see* Characteristics of excluded studies).

### Included studies

#### Study design

All seven studies were parallel design (Cyna 2011; Fisher 2009; Freeman 1986; Harmon 1990; Martin 2001; Mehl-Madrona 2004; Rock 1969) comparing self-hypnosis or hypnotherapy with a control group. Two studies were quasi-randomised controlled trials (Harmon 1990; Rock 1969). Four studies had two groups (Fisher 2009; Freeman 1986; Harmon 1990; Rock 1969), one study had three groups (Cyna 2011) and two studies had two randomised groups plus another 'comparison' group (Martin 2001; Mehl-Madrona 2004) but only the data from the two randomised groups were considered as part of this review. The control groups consisted of the following: standard childbirth preparation (Fisher 2009; Freeman 1986); usual care (Cyna 2011; Rock 1969), a relaxation tape combined with relaxation practice in antenatal classes (Harmon 1990); supportive counselling (Martin 2001); and supportive psychotherapy (Mehl-Madrona 2004). For the purposes of this review supportive psychotherapy, supportive counselling and the relaxation tape with relaxation practice in antenatal classes were treated as attention control conditions where participants received a similar or the same amount of contact as those in the intervention group.

#### Sample sizes

Sample size in the included studies ranged from 38 (Fisher 2009) to 520 (Mehl-Madrona 2004).

#### Study location

Five of the studies were conducted in the USA (Fisher 2009; Harmon 1990; Martin 2001; Mehl-Madrona 2004; Rock 1969), one in the UK (Freeman 1986) and one in Australia (Cyna 2011).

#### Participants

Five studies recruited both nulliparous and multiparous women (Cyna 2011; Fisher 2009; Martin 2001; Mehl-Madrona 2004; Rock 1969) and two studies recruited only nulliparous women (Freeman 1986; Harmon 1990). One study only recruited women aged 18 years or younger (Martin 2001). For further information about inclusion and exclusion criteria for each study, *see* Characteristics of included studies.

#### Types of intervention

In six studies the intervention was antenatal hypnosis training (Cyna 2011; Fisher 2009; Freeman 1986; Harmon 1990; Martin 2001; Mehl-Madrona 2004) which was taught in group classes (Cyna 2011; Fisher 2009; Harmon 1990) or during individual consultations (Freeman 1986; Martin 2001; Mehl-Madrona

2004). In one study, the intervention was hypnosis provided during labour (Rock 1969). One trial had two intervention groups as well as the usual care control group (Cyna 2011). In one intervention group, women listened to 'live' hypnosis in antenatal classes led by a hypnotherapist and a hypnosis audio CD was provided for home practice (Cyna 2011). In the other intervention group, women listened to the same hypnosis audio CD at antenatal classes led by a nurse without training in hypnosis and were also provided with the audio CD for home practice (Cyna 2011). The live hypnosis intervention is similar to the other antenatal self-hypnosis trials so has been included in the main comparisons and all subgroup comparisons for this review. A separate set of comparisons for the nurse/CD group versus control has been reported as Comparison 2 and for a subgroup comparison regarding method of hypnosis.

The hypnosis intervention began in the first or second trimester of pregnancy in one study (Mehl-Madrona 2004), in the second trimester in one study (Martin 2001) and in the third trimester in three studies (Cyna 2011; Freeman 1986; Harmon 1990). The intervention began during labour in one study (Rock 1969). It was not clear when in the pregnancy the intervention began in one study (Fisher 2009). Three studies involved weekly intervention sessions (Cyna 2011; Freeman 1986; Harmon 1990). In one study these sessions started at 32 weeks' gestation and continued until the birth (Freeman 1986). In one study a series of six weekly classes were scheduled (Harmon 1990) and in one study there were three, weekly intervention sessions starting as closely as possible to 37 weeks' gestation (Cyna 2011). In two studies women were also provided with an audio recording for daily practice at home (Cyna 2011; Harmon 1990). In one study there were four intervention sessions spanning approximately eight weeks (Martin 2001). One study reported that women could attend for hypnotherapy as often as desired (subject to therapist availability) (Mehl-Madrona 2004). It was not clear how many intervention sessions were provided for one study (Fisher 2009). In the study where hypnosis was provided during labour, the hypnotherapist was a medical student who also performed routine labour assessments (Rock 1969). The hypnotic induction took an average of 20 minutes and it was reported that the total time added by the hypnotic procedures was 45 minutes longer than with usual care (Rock 1969).

### Outcome measures

The following primary outcomes were reported upon in the studies: use of pharmacological pain relief or anaesthesia during labour and childbirth (Cyna 2011; Fisher 2009; Freeman 1986; Harmon 1990; Martin 2001; Mehl-Madrona 2004; Rock 1969); satisfaction with pain relief (Cyna 2011); sense of coping with labour (Cyna 2011; Fisher 2009) spontaneous vaginal birth (Cyna 2011; Fisher 2009; Freeman 1986; Harmon 1990; Martin 2001; Mehl-Madrona 2004).

The following secondary outcomes were reported upon in the studies: pain intensity (Freeman 1986; Harmon 1990); maternal pain score (Cyna 2011); satisfaction with the childbirth experience (Cyna 2011; Freeman 1986); breastfeeding at hospital discharge (Cyna 2011); assisted vaginal birth (Cyna 2011; Fisher 2009; Freeman 1986; Harmon 1990; Martin 2001; Mehl-Madrona 2004); caesarean section (Cyna 2011; Fisher 2009; Martin 2001; Mehl-Madrona 2004); admission to special care baby unit/ neonatal intensive care unit (Cyna 2011; Martin 2001); Apgar score (Cyna 2011; Fisher 2009; Harmon 1990; Mehl-Madrona 2004); use of epidural (Cyna 2011; Fisher 2009; Freeman 1986; Mehl-Madrona 2004; Rock 1969); length of labour (Cyna 2011; Freeman 1986; Harmon 1990; Martin 2001); induction of labour (Cyna 2011; Harmon 1990; Martin 2001; Mehl-Madrona 2004); augmentation of labour with oxytocin (Cyna 2011; Harmon 1990; Martin 2001; Mehl-Madrona 2004); primary postpartum haemorrhage (Cyna 2011; Mehl-Madrona 2004); need for postpartum blood transfusion (Cyna 2011); postnatal depressive symptoms (Cyna 2011; Harmon 1990; Mehl-Madrona 2004; Rock 1969); number of maternal days in hospital after the birth (Martin 2001) any other adverse events (maternal side effects, newborn resuscitation) (Cyna 2011; Mehl-Madrona 2004).

### Excluded studies

We excluded one study as the hypnotherapeutic programme was not used for pain management during labour and childbirth (Guse 2006) (*see* Characteristics of excluded studies for further details).

## Risk of bias in included studies

*See* Figure 1; Figure 2, for further details regarding 'Risk of bias' assessment.

**Figure 1. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.**

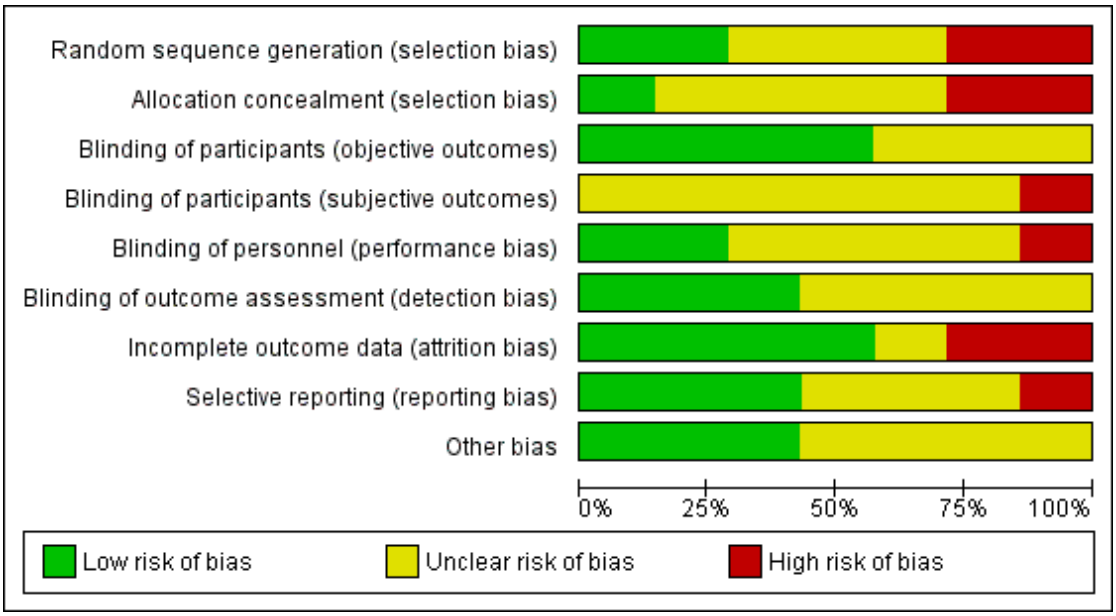
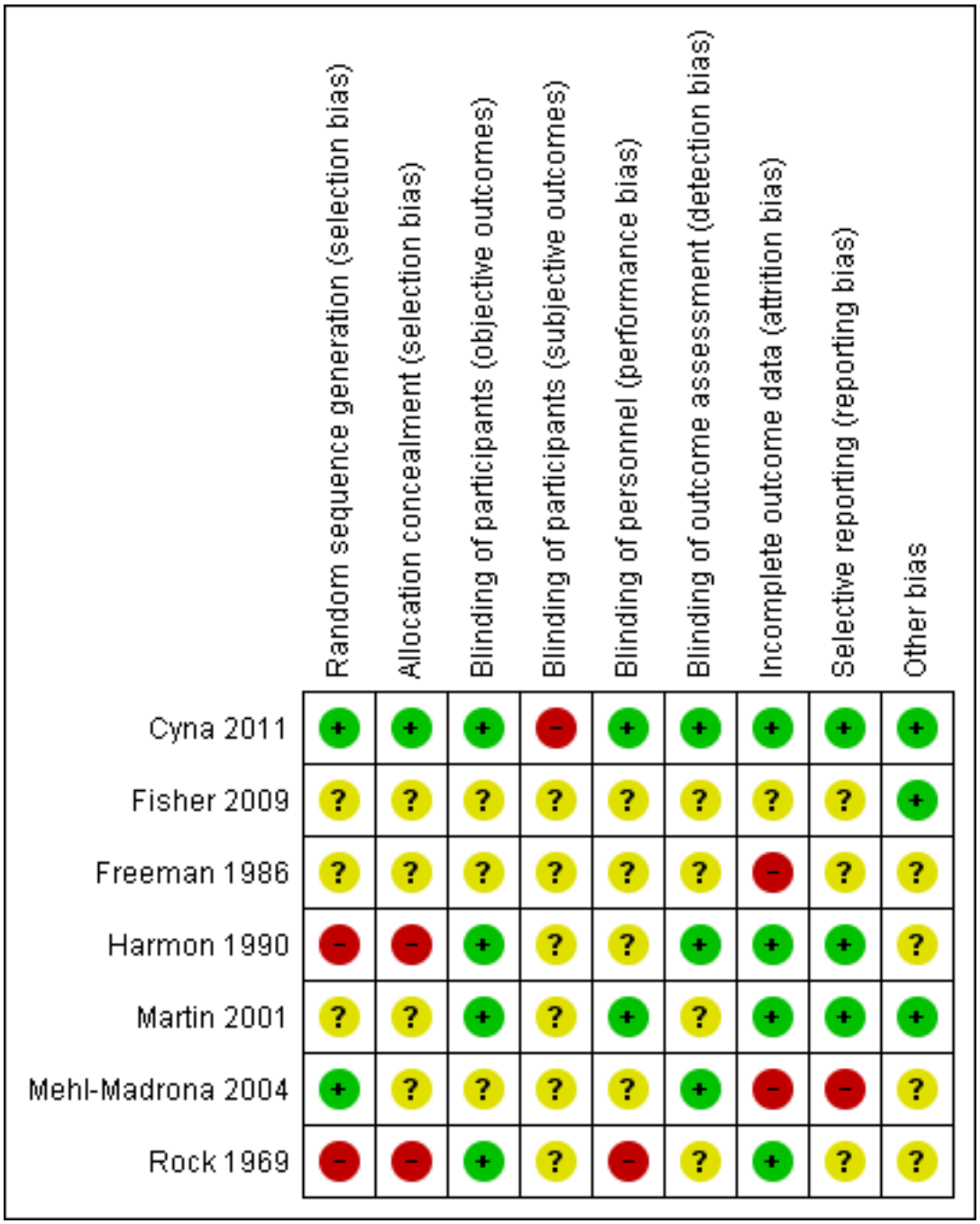


**Figure 2. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.**



### Allocation

Only one of the seven trials (Cyna 2011) had a low risk of bias (using a computer database assignment which was only revealed after patient identifiers had been entered). Two trials were quasi-randomised trials and therefore were at high risk of selection bias (allocated based on hospital number in Rock 1969 and the month the woman was due in Harmon 1990). The other four trials were assessed as having an unclear risk of selection bias as they did not report how group allocation was concealed.

### Blinding

Blinding of participants is difficult for hypnosis interventions but four trials reported that women were not told which group they were allocated to (Cyna 2011; Harmon 1990; Martin 2001; Rock 1969). We considered that participants knowledge of their group allocation may have an impact on subjective outcomes (such as satisfaction with pain relief) but was unlikely to have an impact on objective outcomes (such as spontaneous vaginal birth). We assessed risk of bias separately for subjective and objective outcomes where studies reported that blinding of participants had been attempted. Four studies (57%) were rated as low risk of bias for objective outcomes (Cyna 2011; Harmon 1990; Martin 2001; Rock 1969). Three studies (43%) were rated as unclear risk of bias for subjective outcomes (Harmon 1990; Martin 2001; Rock 1969) as women were not told their group allocation but there was no reporting about whether blinding was successful. Only one trial (14%) reported data about the success of blinding for participants (Cyna 2011). This trial was rated at high risk of bias for subjective outcomes as results showed that none of the women in the control group believed they were in a hypnosis group and more than 70% of women in the two intervention groups believed they were in a hypnosis group (Cyna 2011). Three studies (43%) were rated as unclear risk of bias for blinding of participants overall (Fisher 2009; Freeman 1986; Mehl-Madrona 2004) as they did not report whether any attempt was made to blind the women to their group allocation.

It is not possible for personnel providing hypnosis interventions to be blinded to the intervention but it is possible for personnel caring for a woman in labour to be blinded so assessment of blinding of personnel in this review relates to blinding of the personnel who cared for the woman during labour. Blinding of personal was assessed as low risk of bias in two studies (Cyna 2011; Martin 2001) (29%) and at high risk of bias for one trial (Rock 1969) (14%). The risk of bias was unclear in the remaining studies (Fisher 2009; Freeman 1986; Harmon 1990; Mehl-Madrona 2004) (57%) as there was no reporting of whether personnel were blinded to group allocation.

Blinding of outcome assessment was at low risk of bias in three studies (Cyna 2011; Harmon 1990; Mehl-Madrona 2004) (43%) and unclear in the remaining studies (57%). Two studies did not report whether outcome assessors were blinded to group allocation (Fisher 2009; Freeman 1986) and in two studies it was unclear from what was reported whether outcome assessors were blinded (Martin 2001; Rock 1969).

### Incomplete outcome data

Four of the trials (57%) were rated as low risk of bias for incomplete outcome data (Cyna 2011; Harmon 1990; Martin 2001; Rock 1969). In one trial the intervention was provided in labour and no losses of participants were reported (Rock 1969). In one study all primary and secondary outcomes for eligible trial participants were analysed using the intention-to-treat principle (Cyna 2011). In one trial one woman was excluded following randomisation after becoming ineligible for inclusion in the study (Harmon 1990). In one trial the reasons for the five participants lost to follow-up were unlikely to have been related to the intervention or were balanced between groups (three moved out of the geographic area and one from each group did not complete the research protocol) (Martin 2001). Two trials were assessed as high risk of bias (Freeman 1986; Mehl-Madrona 2004) (29%). In one trial losses appeared to be related to the intervention, four participants from the hypnosis condition were excluded as they did not attend for hypnosis ( Freeman 1986). In the other trial, women from the hypnosis group were excluded from data analysis if they were diagnosed with a range of mental illnesses but it was unclear whether women from the control group were excluded on the same basis (Mehl-Madrona 2004). In the remaining study risk of bias for incomplete outcome data was unclear (14%) as there was no reporting of how many participants were lost (Fisher 2009).

### Selective reporting

Three of the trials (43%) were rated as low risk of bias for selective outcome reporting (Cyna 2011; Harmon 1990; Martin 2001). In one trial all of the outcomes listed in the trial registration were reported or provided (Cyna 2011) and in two trials all of the outcomes listed in the hypotheses were reported (Harmon 1990; Martin 2001). One study (14%) was assessed as being at high risk of bias (Mehl-Madrona 2004) as not all of the outcomes outlined in the study were fully reported. In the remaining three studies (43%) risk of bias for was unclear (Fisher 2009; Freeman 1986; Rock 1969) as one report was a conference abstract so detailed data were not reported (Fisher 2009) and two studies reported narrative descriptions with P values without frequency data for one outcome (Freeman 1986; Rock 1969).

### Other potential sources of bias

Three of the trials (43%) were rated as being at low risk of bias for other bias (Cyna 2011; Fisher 2009; Martin 2001) based on balance in demographic characteristics of participants at baseline and no other issues of concern identified. In the remaining four studies (57%) risk of bias was unclear (Freeman 1986; Harmon 1990; Mehl-Madrona 2004; Rock 1969) as little or no demographic data were reported for the intervention and control groups.

## Effects of interventions

### Self-hypnosis or hypnotherapy versus control

#### Primary outcomes

#### Use of pharmacological pain relief or anaesthesia during labour and childbirth

All seven studies measured this outcome (Cyna 2011; Fisher 2009; Freeman 1986; Harmon 1990; Martin 2001; Mehl-Madrona 2004; Rock 1969) but one study did not report any numerical data so could not be included in the analysis (Fisher 2009). Two studies (Harmon 1990; Rock 1969) reported the use of tranquillizers but these were not considered to be pain relief for the purposes of this review. Therefore, the data for Harmon 1990 and Rock 1969 used in this outcome relate to the use of narcotics only. One study (Freeman 1986) combined women who used the inhaled analgesic Entonox with those who used no analgesia so only those who were reported as using pethidine and/or epidural were included as using pharmacological pain relief or anaesthesia.

There was a trend towards women in the hypnosis group being less likely to use pharmacological pain relief or anaesthesia during labour and childbirth, but the difference between groups did not reach statistical significance (P = 0.06, average risk ratio (average RR) 0.63, 95% confidence interval (CI) 0.39 to 1.01, six studies, 1032 women). There was substantial statistical heterogeneity: $I^2$ = 95%, $T^2$ = 0.30, $Chi^2$ test for heterogeneity P < 0.01, and so we used a random-effects model, Analysis 1.1. It is likely that the Harmon 1990 and Mehl-Madrona 2004 trials contributed to the high level of heterogeneity. The Harmon 1990 trial was a quasi-randomised controlled trial so is subject to a high risk of selection bias. The other quasi-randomised controlled trial (Rock 1969) also favoured hypnosis but not as strongly as the Harmon 1990 or Mehl-Madrona 2004 trials. For the Mehl-Madrona 2004 trial it is not clear whether the timing of the intervention and/or some other characteristic of the trial explains the result strongly favouring the intervention.

Subgroup analysis indicated that there was an interaction between the trimester at commencement of hypnosis sessions and use of pharmacological analgesia (test for subgroup differences P = 0.009, $I^2$ = 79%, (Analysis 1.1). In one trial (n = 520), women commenced hypnosis in the first or second trimester (RR 0.42, 95% CI 0.33 to 0.52). In one trial (n = 42), women commenced hypnosis in the second trimester (RR 0.65, 95% CI 0.38 to 1.11). In four trials (n = 470), women commenced hypnosis in the third trimester (average RR 0.78, 95% CI 0.55 to 1.12). Thus the use of pharmacological analgesia appeared to be lower when women commenced hypnosis in the first or second trimester. However, data were only available for one trial where the intervention was provided in the first or second trimester (Mehl-Madrona 2004) so, as noted above, it is not clear whether the result was related to the timing of the intervention and/or some other characteristic of the trial.

As noted, one trial had a second intervention; this group of women listened to an audio CD of hypnosis as part of antenatal sessions with a nurse without training in hypnotherapy (Cyna 2011). This group will be referred to as the 'nurse/audio CD group'. No significant difference was found in the proportion of women who used pharmacological pain relief or analgesia in the nurse/audio CD group compared with the control group (RR 1.01, 95% CI 0.89 to 1.15, one study, 294 women), Analysis 2.1.

#### Satisfaction with pain relief

One study reported on this outcome (Cyna 2011). There was no significant difference identified between the hypnosis and control group in the proportion of women who reported that they received adequate pain relief (RR 1.06, 95% CI 0.94 to 1.20, one study, 264 women), Analysis 1.2. There was also no significant difference in the proportion of women who reported they received adequate pain relief between the nurse/CD group and the control group (RR 0.91, 95% CI 0.78 to 1.05, one study, 259 women), Analysis 2.2.

#### Sense of coping with labour

Two studies reported upon this outcome (Cyna 2011; Fisher 2009) but no frequency data were reported so the data were unable to be analysed as part of the review. Cyna 2011 reported women's perceptions of coping with childbirth postnatally prior to their discharge from hospital stating that there was no difference in median interquartile ranges (IQR) 7(3) versus 8(3) on a 10-point scale. Fisher 2009 reported: "a greater ability to cope during childbirth after hypnosis course completion compared to the conventional group. However, after delivery, the hypnosis group recalled relatively poorer intrapartum coping skills (P = 0.02)."

#### Spontaneous vaginal birth

Six studies reported on this outcome (Cyna 2011; Fisher 2009; Freeman 1986; Harmon 1990; Martin 2001; Mehl-Madrona 2004), but data were only available for analysis from four studies (Cyna 2011; Freeman 1986; Harmon 1990; Martin 2001). One

trial did not report numerical data for this outcome (Fisher 2009) and one trial reported data grouped as 'uncomplicated births' and 'complicated births' (Mehl-Madrona 2004). Although the uncomplicated births group only included spontaneous vaginal births, the complicated births group included both spontaneous vaginal births and surgically assisted births. This meant that the overall number of spontaneous vaginal births could not be calculated (for example, if a woman had a spontaneous vaginal birth followed by a postpartum haemorrhage she was included in the complicated birth group) (Mehl-Madrona 2004).

No significant difference was found between the hypnosis and control group in the proportion of women having a spontaneous vaginal birth (average RR 1.35, 95% CI 0.93 to 1.96, four studies, 472 women). There was substantial statistical heterogeneity: $I^2$ = 82%, $T^2$ = 0.11, $Chi^2$ test for heterogeneity P < 0.01, and so we used a random-effects model, Analysis 1.3. It is likely that the Martin 2001 trial contributed to the high level of heterogeneity. This trial included only women aged 18 years or younger and involved hypnosis preparation for labour provided one-on-one from the second trimester. It is not clear which, if any, of these factors may help explain the heterogeneity.

Subgroup analysis indicated that there was an interaction between trimester at commencement of hypnosis sessions and spontaneous vaginal birth (test for subgroup differences P = 0.02, $I^2$ = 82.4%, Analysis 1.3). In one trial (n = 42), women commenced hypnosis in the second trimester (RR 2.42, 95% CI 1.43 to 4.07). In three trials (n = 430), women commenced hypnosis in the third trimester (average RR 1.16, 95% CI 0.85 to 1.57). Thus the likelihood of spontaneous vaginal birth appeared to be greater when women commenced hypnosis in the second trimester. However, data were only available for one trial where the intervention was provided in the second trimester (Martin 2001) so it is not clear whether the result was related to the timing of the intervention and/or some other characteristic of the trial.

There was no significant difference in the proportion of women who had a spontaneous vaginal birth between those in the nurse/audio CD group compared with those in the control group (RR 0.96 95% CI 0.80 to 1.16, one study, 294 women), Analysis 2.3.

### Secondary outcomes

#### Pain intensity

Two studies reported on this outcome (Freeman 1986; Harmon 1990), but data were only available for analysis from one study (Harmon 1990). In the other study no numerical data were reported but it was noted that there was no significant difference between the two groups in terms of efficacy of pain relief on a linear analogue scale (Freeman 1986).

The mean pain score in the hypnosis group was significantly lower than the mean pain score in the control group according to the present pain intensity scale of the McGill Pain Questionnaire, (where, 0 = No pain, 1 = Mild, 2 = Discomforting, 3 = Distressing, 4 = Horrible, 5 = Excruciating), (mean difference (MD) -0.70, 95% CI-1.03 to -0.37, one study, 60 women), Analysis 1.4.

#### Maternal pain score as measured by visual analogue pain scores of verbal numerical rating scales

One study reported on this outcome (Cyna 2011), but the results were reported as medians (Mdn) and interquartile ranges (IQR) (as is appropriate for ordinal level data) so was not in a format suitable for analysis as part of the review. However no significant differences were reported between the scores for the hypnosis group (Mdn 8, IQR 2), the control group (Mdn 8, IQR 2) and the nurse/CD only group (Mdn 8, IQR 2).

#### Satisfaction with the childbirth experience

Two studies reported on this outcome (Cyna 2011; Freeman 1986). One study measured this outcome as the number of women who reported being "very satisfied" (score 8-10 on linear analogue scale) with labour (Freeman 1986) and the other trial measured it as the number of women who reported the birth as a positive experience (Cyna 2011).

No significant difference was found for satisfaction with the childbirth experience between women in the hypnosis group and women in the control group (average RR 1.36, 95% CI 0.52 to 3.59, two studies, 370 women). There was substantial statistical heterogeneity: $I^2$ = 87%, $T^2$ = 0.43, $Chi^2$ test for heterogeneity P < 0.01, and so we used a random-effects model, Analysis 1.5. As there were only two trials, it is not clear which differences between the trials could explain this heterogeneity, for example, the Freeman 1986 trial was much smaller, the hypnosis intervention began earlier in the pregnancy and involved more sessions than the Cyna 2011 trial.

No significant difference was found between the nurse/audio CD group and the control group for satisfaction with the childbirth experience (RR 0.94, 95% CI 0.83 to 1.07, one study, 294 women), Analysis 2.4.

#### Breastfeeding at discharge

One study reported on this outcome (Cyna 2011). There was no significant difference in the proportion of women who reported any breastfeeding at discharge from hospital between the hypnosis group and the control group (RR 1.00, 95% CI 0.97 to 1.03, one study, 304 women), Analysis 1.6. There was also no significant difference between the nurse/audio CD group and the control group for this outcome (RR 1.01, 95% CI 0.98 to 1.04, one study, 294 women), Analysis 2.5.

### Assisted vaginal birth

Six studies measured this outcome (Cyna 2011; Freeman 1986; Fisher 2009, Harmon 1990; Martin 2001; Mehl-Madrona 2004) but data were only available for analysis from four studies (Cyna 2011; Freeman 1986; Harmon 1990; Martin 2001). One study did not report numerical data for this outcome (Fisher 2009) and one study grouped assisted vaginal births within a complicated birth group which included a range of complications as outlined above (Mehl-Madrona 2004).

No significant difference was found in the proportion of women who had assisted vaginal births between the women in the hypnosis group and those in the control group (average RR 0.61, 95% CI 0.32 to 1.15, four studies, 474 women). There was substantial statistical heterogeneity: $I^2$ = 52%, $T^2$ = 0.20, $Chi^2$ test for heterogeneity P = 0.10, and so we used a random-effects model, Analysis 1.7. It does not appear that any individual trial was responsible for this heterogeneity.

No significant difference was found between women in the nurse/audio CD group and women in the control group for assisted vaginal birth (RR 1.20, 95% CI 0.78 to 1.85, one study, 294 women), Analysis 2.6.

### Caesarean section

Four studies reported upon this outcome (Cyna 2011; Fisher 2009; Martin 2001; Mehl-Madrona 2004), but one study did not report numerical data so was not able to be included in the analysis (Fisher 2009). No significant difference was found in the proportion of women who had a caesarean section between those in the hypnosis group and the control group (average RR 0.58, 95% CI 0.20 to 1.65, three studies, 867 women). There was substantial statistical heterogeneity: $I^2$ = 86%, $T^2$ = 0.60, $Chi^2$ test for heterogeneity P < 0.01, and so we used a random-effects model, Analysis 1.8. It is likely that the Martin 2001 trial contributed to the high level of heterogeneity. This trial included only women aged 18 years or younger and involved hypnosis preparation for labour provided one-on-one from the second trimester. It is not clear which, if any, of these factors may help explain the heterogeneity.

There was no significant difference between women in the nurse/audio CD group and women in the control group for caesarean section (RR 0.91, 95% CI 0.56 to 1.48, one study, 294 women), Analysis 2.7.

### Admission to special care baby unit/neonatal intensive care unit

Two studies reported on this outcome (Cyna 2011; Martin 2001). No significant difference was found for admissions to the neonatal intensive care unit for babies born to the mothers in the hypnosis group compared with babies born to mothers in the control group (average RR 0.58, 95% CI 0.12 to 2.89, two studies, 347 women). There was substantial statistical heterogeneity: $I^2$ = 63%, $T^2$ = 0.96, $Chi^2$ test for heterogeneity P = 0.10, and so we used a random-effects model, Analysis 1.9. As there were only two trials, it is possible that differences between the trials could explain this heterogeneity. For example, the Martin 2001 trial was small, the women were all aged 18 years or younger and the hypnosis intervention began earlier in the pregnancy and involved more sessions than the Cyna 2011 trial.

There was no significant difference between women in the nurse/audio CD group and women in the control group for babies admitted to the neonatal intensive care unit (RR 0.93, 95% CI 0.67 to 1.29, one study, 294 women), Analysis 2.8.

### Apgar score less than seven at five minutes

Four studies reported on this outcome (Cyna 2011; Fisher 2009; Harmon 1990; Mehl-Madrona 2004), but two trials did not report numerical data so were unable to be included in the analysis (Fisher 2009; Mehl-Madrona 2004).

No significant difference was found in the proportion of babies who had Apgar scores less than seven at five minutes between the women in the hypnosis group and the control group (average RR 0.49, 95% CI 0.04 to 5.35, two studies, 365 women), Analysis 1.10. There was also no significant difference between women in the nurse/audio CD group and women in the control group for this outcome (RR 0.53, 95% CI 0.05 to 5.76, one study, 294 women), Analysis 2.9.

### Use of epidural/neuroaxial block

Five studies reported on this outcome (Cyna 2011; Fisher 2009; Freeman 1986; Mehl-Madrona 2004; Rock 1969), but one trial did not report numerical so was not able to be included in the analysis (Fisher 2009).

No significant difference was found in the proportion of women having an epidural between the hypnosis and control group (average RR 0.76, 95% CI 0.29 to 2.02, four studies, 930 women). There was substantial statistical heterogeneity: $I^2$ = 94%, $T^2$ = 0.74, $Chi^2$ test for heterogeneity P < 0.01, and so we used a random-effects model, Analysis 1.11. It appears that the Mehl-Madrona 2004 trial was responsible for the high level of heterogeneity. This trial provided unlimited one-on-one hypnotherapy commencing in the first or second trimester and was judged to be at high risk of attrition bias. It is not clear which of these factors, if any, contributed to the results strongly favouring hypnosis.

There was no significant difference found between women in the nurse/audio CD group and the control group for use of epidural/neuroaxial block (RR 0.94, 95% CI 0.73 to 1.20, one study, 294 women), Analysis 2.10.

### Length of labour

Four studies reported on this outcome (Cyna 2011; Freeman 1986; Martin 2001; Harmon 1990). Three trials did not report data

in a format that could be included in the review (Cyna 2011; Freeman 1986; Martin 2001). One of these trials reported that women in the hypnosis group had significantly longer labours P < 0.05 (Freeman 1986) and another (Cyna 2011) no difference - median (IQR) of 8 (7.3) hours for hypnosis versus 7.4 (6.7) hours for control women. The other trial reported that no significant differences were found in the perceived hours of each stage of labour between the groups (Martin 2001).

In the one study where data were available (n = 60), the mean length of labour (measured as number of minutes from 5 cm dilation to birth) in the hypnosis group was significantly shorter than for the women in the control group, (MD -165.20, 95% CI -223.53 to -106.87), Analysis 1.12.

### Induction of labour

Four studies reported on this outcome (Cyna 2011; Harmon 1990; Martin 2001; Mehl-Madrona 2004) but two studies could not be included in the analysis as they reported induction and augmentation data combined (Martin 2001; Mehl-Madrona 2004). Both of those studies reported that women in the hypnosis group had less induction or augmentation, two of the 22 women in the hypnosis compared with six of the 20 women in the Martin 2001 trial and 22 of the 260 women in the hypnosis group compared with 72 of the 260 women in the control group in the Mehl-Madrona 2004 trial.

No significant difference was found in the proportion of women whose labour was induced between the hypnosis group and the control group (average RR 0.80, 95% CI 0.26 to 2.46, two studies, 365 women). There was substantial statistical heterogeneity: $I^2$ = 82%, $T^2$ = 0.55, $Chi^2$ test for heterogeneity P = 0.02, and so we used a random-effects model, Analysis 1.13. As there were only two trials, it is not clear whether differences in the interventions or trial designs would explain this heterogeneity. However, Harmon 1990 was a quasi-randomised controlled trial so is subject to a high risk of selection bias.

There was no significant difference found between women in the nurse/audio CD group and women in the control group for induction of labour (RR 0.97, 95% CI 0.68 to 1.36, one study, 294 women), Analysis 2.11.

### Augmentation with oxytocin

Four studies reported on this outcome (Cyna 2011; Harmon 1990; Martin 2001; Mehl-Madrona 2004) but three studies could not be included in the analysis. Two of the studies reported induction and augmentation data combined as noted above (Martin 2001; Mehl-Madrona 2004). One of the trials reported induction data separately as well as overall use of oxytocics but did not provide data for augmentation alone (Harmon 1990). That study reported that nine of the 30 women in the hypnosis group used oxytocics at some stage in labour compared with 29 of 30 women in the control group (Martin 2001).

No significant difference was found in the proportion of women who had their labour augmented between those in the hypnosis group and the control group (RR 0.98, 95% CI 0.76 to 1.27, one study, 305 women), Analysis 1.14. There was also no significant difference found between women in the nurse/audio CD group and women in the control group for this outcome (RR 1.06, 95% CI 0.82 to 1.36, one study, 294 women), Analysis 2.12.

### Primary postpartum haemorrhage (greater than 500 mL)

Two studies reported on this outcome (Cyna 2011; Mehl-Madrona 2004) but data from one study were reported in a combined 'complicated birth' category so could not be included in the analysis (Mehl-Madrona 2004).

No significant difference was found in the proportion of women who had a primary postpartum haemorrhage between the hypnosis group and the control group (RR 1.68, 95% CI 0.90 to 3.12, one study, 305 women), Analysis 1.15. There was also no significant difference found between women in the nurse/audio CD group and women in the control group for this outcome (RR 1.66, 95% CI 0.88 to 3.12, one study, 294 women), Analysis 2.13.

### Need for postpartum blood transfusion

One trial reported on this outcome (Cyna 2011). No significant difference was found in the proportion of women who needed a postpartum blood transfusion between those in the hypnosis group and the control group (RR 3.92, 95% CI 0.44 to 34.69, one study, 305 women), Analysis 1.16. There was also no significant difference found between women in the nurse/audio CD group and women in the control group although there was a trend towards women in the nurse/audio CD group being more likely to need a postpartum blood transfusion (P = 0.06, RR 7.39, 95% CI 0.92 to 59.33, one study, 294 women), Analysis 2.14.

### Postnatal depressive symptoms

Four studies reported on this outcome (Cyna 2011; Harmon 1990; Mehl-Madrona 2004; Rock 1969), but data were not available in a suitable format for analysis from two trials. The author of one trial advised that women were followed up at one month and that "there were no cases of significant post-partum depression during that month in either group" but it was not clear how many participants were able to be contacted for this follow-up (Mehl-Madrona 2004). The other trial reported mean T scores on the Minnesota Multiphasic Personality Inventory (MMPI) Depression scale for high and low hypnotic susceptibility groups for the intervention and control groups. It was reported that there was an interaction effect of hypnosis with susceptibility P < 0.05 and that only the highly susceptible, hypnotically-trained women had lower MMPI depression scale scores (Harmon 1990).

The two trials that did report data were clinically heterogeneous; one provided antenatal training in self-hypnosis (Cyna 2011) and

one provided hypnosis during labour (Rock 1969). One of the trials (Rock 1969), had no events in either group. No significant difference was found in the proportion of women who reported post-natal depressive symptoms between those in the hypnosis group and the control group (average RR 1.17, 95% CI 0.77 to 1.78, two studies, 345 women), Analysis 1.17. There was also no significant difference found between women in the nurse/audio CD group and women in the control group for this outcome (RR 0.82, 95% CI 0.51 to 1.32, one study, 294 women), Analysis 2.15.

### Number of maternal days in hospital after the birth

One study reported upon this outcome (Martin 2001). There were fewer women in the hypnosis group compared with the control group, who stayed in hospital for more than two days after the birth, (RR 0.11, 95% CI 0.02 to 0.83, one study, 42 women), Analysis 1.18.

### Any other adverse events (maternal side effects, newborn resuscitation)

Two studies reported data that have been included for this outcome (Cyna 2011; Mehl-Madrona 2004). One study reported on newborn resuscitations (Mehl-Madrona 2004). No significant difference was found in the proportion of babies who received resuscitation as newborns between women in the hypnosis group and those in the control group (RR 0.67, 95% CI 0.11 to 3.96, one study, 520 women), Analysis 1.19.

One study reported on maternal readmissions to hospital, neonatal readmissions to hospital and maternal admissions to the high dependency unit or intensive care unit (Cyna 2011). No significant difference was found in the proportion of women who were readmitted to hospital between those in hypnosis group and the control group (RR 1.56, 95% CI 0.62 to 3.90, one study, 267 women), Analysis 1.20. There was also no significant difference found between women in the nurse/audio CD group and women in the control group for this outcome (RR 1.14, 95% CI 0.43 to 3.06 one study, 266 women), Analysis 2.16.

No significant difference was found in the proportion of babies who were readmitted to hospital between women who were in the hypnosis group and those in the control group (RR 1.39, 95% CI 0.64 to 3.02, one study, 267 women), Analysis 1.21, or between women in the nurse/audio CD group and women in the control group (RR 0.90, 95% CI 0.38 to 2.14, one study, 266 women), Analysis 2.17.

No significant difference was found in the proportion of women who were admitted to the high dependency or intensive care unit between women in the hypnosis group and those in the control group (RR 1.47, 95% CI 0.25 to 8.68, one study, 305 women), Analysis 1.22. There was also no significant difference found between women in the nurse/audio CD group and women in the control group for this outcome (RR 3.70, 95% CI 0.78 to 17.50, one study, 294 women), Analysis 2.18.

### Sensitivity analysis

Sensitivity analysis was undertaken for the primary outcomes by excluding the two quasi-randomised controlled trials (Harmon 1990; Rock 1969) as these were at high risk of bias for selection bias. With the quasi-randomised studies included there was a trend towards women in the hypnosis group being less likely to use pharmacological pain relief or anaesthesia during labour and childbirth, but the difference between groups did not reach statistical significance (P = 0.06, average RR 0.63, 95% CI 0.39 to 1.01, six studies, 1032 women), Analysis 1.1. This trend was not found when the quasi-randomised controlled trials were excluded for this outcome (P = 0.29, average RR 0.73, 95% CI 0.41 to 1.30, four studies, 932 women).

Only one of the quasi-randomised controlled trials provided data for the spontaneous vaginal birth outcome (Harmon 1990). The results with this trial included found no significant difference between women in the hypnosis group and women in the control group (average RR 1.35, 95% CI 0.93 to 1.96, four studies, 472 women), Analysis 1.3. Similarly, no significant difference was found when the Harmon 1990 trial was excluded (average RR 1.29, 95% CI 0.83 to 2.00, three studies, 412 women).

No data from the quasi-randomised controlled trials were available for the other primary outcomes.

### Subgroup analysis

A relatively large number of subgroup analyses were planned to investigate potential sources of heterogeneity. Some of these analyses were specified by the generic protocol (Jones 2011) and others were specific to this review. Three of the subgroup analyses specified in the generic protocol (spontaneous labour versus induced labour; term versus preterm birth; and continuous support in labour versus no continuous support) were not applicable for this review as the hypnosis intervention was generally provided during the antenatal period rather than during labour. Those subgroups divided participants according to characteristics that occurred after randomisation and therefore were not baseline characteristics for this intervention. In addition, no data were available for the prespecified subgroup analysis of maternal anxiety levels (high versus low) so this was not performed. All subgroup analyses were prespecified although the groupings for trimester and audio CD were amended to include all available data.

Subgroup analyses were restricted to the primary outcomes and data were only available for two outcomes, use of pharmacological pain relief or analgesia and spontaneous vaginal birth. For use of pharmacological pain relief or analgesia, the following subgroup analyses did not explain the heterogeneity: nulliparous versus multiparous women (P = 0.33) Analysis 3.1, group versus one-to-one hypnosis sessions (P = 0.78) Analysis 5.1, hypnosis plus audio CD/tape versus hypnosis no audio CD/tape versus nurse/audio CD only (P = 0.54) Analysis 6.1, hypnosis preparation for labour versus hypnosis during labour (P = 0.79) Analysis 7.1, and high versus

low hypnotisability (P = 0.81) Analysis 8.1. Similarly, these subgroups did not explain the heterogeneity for spontaneous vaginal birth: nulliparous versus multiparous women (P = 0.97) Analysis 3.2, group versus one-to-one hypnosis sessions (P = 0.47) Analysis 5.2, hypnosis plus audio CD/tape versus hypnosis no audio CD/tape versus nurse/audio CD only (P = 0.36) Analysis 6.2, and high versus low hypnotisability (P = 0.85) Analysis 8.2.

As noted in the main results, there were interactions between trimester at commencement of hypnosis sessions and use of pharmacological analgesia (P = 0.009) Analysis 1.1, and spontaneous vaginal birth (P = 0.02) Analysis 1.3. The use of pharmacological analgesia appeared to be lower when women commenced hypnosis in the first or second trimester and the likelihood of spontaneous vaginal birth appeared to be greater when women commenced hypnosis in the second trimester.

There were also interactions between the number of hypnosis session (less than four sessions versus four or more sessions) and use of pharmacological analgesia (P = 0.04) Analysis 4.1, and spontaneous vaginal birth (P = 0.01) Analysis 4.2. For use of pharmacological analgesia, in one trial (n = 305) women had less than four sessions of antenatal training (RR 1.07, 95% CI 0.95 to 1.20), Analysis 4.1.1. In four trials (n = 687), women had four or more antenatal sessions (average RR 0.52, 95% CI 0.27 to 1.01) Analysis 4.1.2. The use of pharmacological analgesia appeared to be lower for women who had four or more sessions of hypnosis than for those who had less than four sessions. For spontaneous vaginal birth, one trial (n = 305) had less than four antenatal training sessions (RR 0.91, 95% CI 0.75 to 1.10) Analysis 4.2.1 and three trials (n = 167) had four or more antenatal sessions (average RR 1.59, 95% CI 1.06 to 2.38) Analysis 4.2.2. Spontaneous vaginal birth appeared to be associated with four or more sessions of antenatal hypnosis.

These results should be treated with caution as subgroup comparisons are observational in nature and are subject to the limitations of any observational investigation (Higgins 2011). It should also be noted that there was substantial statistical heterogeneity within the subgroups for both commencement of hypnosis in the 3rd trimester and for four or more sessions of hypnosis. For example, for use of pharmacological analgesia within the 3rd trimester subgroup $I^2$ = 84%, $T^2$ = 0.10, $Chi^2$ test for heterogeneity P < 0.01. There was a lack of data for the other subgroups with only one study able to be included in each group, Analysis 1.1. This increases the caution which should be used in interpreting the results of these subgroup analyses.

# DISCUSSION

## Summary of main results

We included seven trials randomising a total of 1213 women. These trials were mostly at moderate to high risk of bias. For the primary outcomes, no significant differences were found between women in the hypnosis group and those in the control group regarding satisfaction with pain relief or spontaneous vaginal birth. There was a trend towards women in the hypnosis group being less likely to use pharmacological pain relief or analgesia than those in the control group, although the result did not reach statistical significance (P = 0.06, average risk ratio (RR) 0.63, 95% confidence interval (CI) 0.39 to 1.01, six studies, 1032 women). However, there was statistically significant heterogeneity.

For secondary outcomes, no significant differences were found between women in the hypnosis group and women in the control group for most outcomes where data were available.There was some evidence of benefits for women in the hypnosis group compared with the control group for pain intensity, length of labour and maternal hospital stay, but these findings were based on single studies with small numbers of women. Pain intensity was found to be lower for women in the hypnosis group than those in the control group in one trial of 60 women (mean difference (MD) -0.70, 95% CI -1.03 to -0.37). The same study found that the average length of labour in minutes from 5 cm dilation to birth was significantly shorter for women in the hypnosis group (MD -165.20, 95% CI -223.53 to -106.87, one study, 60 women). Another study found that a smaller proportion of women in the hypnosis group stayed in hospital for more than two days after the birth compared with women in the control group (RR 0.11, 95% CI 0.02 to 0.83, one study, 42 women). No significant differences between women in the hypnosis and control groups were found for satisfaction with the childbirth experience, breastfeeding at hospital discharge, assisted vaginal birth, caesarean section, admission to special care baby unit/neonatal intensive care unit, Apgar score, use of epidural, induction of labour, augmentation of labour with oxytocin, primary postpartum haemorrhage, need for postpartum blood transfusion, postnatal depressive symptoms or any other adverse events (newborn resuscitation, maternal admission to the high dependency/intensive care unit or maternal or newborn readmission to hospital). No data were available in a format suitable for analysis for the other outcome measures.

## Overall completeness and applicability of evidence

Five of the trials were undertaken in the USA, one trial in the UK and one in Australia. Only two of the trials included a large number of randomly assigned participants; 520 women in the largest trial (Mehl-Madrona 2004) and 448 for the other large trial (Cyna 2011). The other trials reported data for less than 70 participants (Fisher 2009; Freeman 1986; Harmon 1990; Martin 2001; Rock 1969) and two of these studies were quasi-randomised controlled trials (Harmon 1990; Rock 1969). Inclusion and exclusion criteria were reported. Generally trials included low-risk nul-

liparous and multiparous women. Most studies involved teaching women self-hypnosis in group classes or individual consultations and this reflects clinical practice. Most studies did not provide detailed descriptions of the hypnotic suggestions used but three of the studies Cyna 2011; Harmon 1990; Martin 2001 did provide sufficient information about the intervention to be generalisable in other settings. None of the studies provided information about the economic costs of the intervention, however, it is likely that group programs would be less resource intensive than one-on-one interventions, which may affect clinical applicability. Suggestions have been made for research incorporating cost-benefit analyses and other issues which may affect clinical generalisability (see Implications for research). The studies did not report the number of women who were approached to consider participating in the trial compared with the number who were recruited and randomised. This data would also assist in assessing the generalisability of the findings. One study did report data regarding 50 potentially eligible women who expressed some interest in the trial but eventually declined to participate (Cyna 2011). Most of the women (58%) did not state their reason, 24% indicated they felt their pregnancy was too advanced to attend sessions, 14% reported they definitely wanted hypnosis and 4% reported being too tired to attend all sessions (Cyna 2011).

Only a few studies reported detailed demographic data for participants. One study specifically recruited teenaged women (Martin 2001). Only one study compared participants with the general population of pregnant women (Cyna 2011). In that study, more than 55% of participants reported they had a tertiary education, a much higher proportion than the average among the pregnant population of that state generally (Cyna 2011). The author noted "This study population was more highly educated and older than the general pregnant population of South Australia which may have affected the generalisability of our study findings" (Cyna 2011).

There was wide variation in the number of hypnosis sessions included in the intervention and the gestation when sessions commenced. This was explored as part of the subgroup comparisons which indicated that hypnosis earlier in pregnancy or involving more sessions may be beneficial. It is clinically plausible that hypnosis preparation earlier in the pregnancy and involving a greater number of sessions may be beneficial, particularly for self-hypnosis. Self-hypnosis is a skill, which can be learned, and in this context it is a skill which needs to be applied under the physical and psychological challenges of labour. There also is some evidence that hypnotic response can improve with repeated sessions (Lewis 1992). These results should be treated with caution due to the observational nature of subgroup comparisons. However, in addition, it is worth noting that the studies also reported very wide variations in women's actual attendance and practice of the techniques. For example, in one trial, in addition to attending six prenatal training sessions, participants reported practicing with an audio-recording a mean number of 28 times individually and five times as a couple (Harmon 1990). By comparison, another study reported that "Only 26.0% of women in the Hypnosis Group and 30.8% in the CD group actually complied with all parts of the intervention, - i.e. they attended all sessions and listened at least once to each of the four CDs" (Cyna 2011). These observations may be useful in planning future trials or for women interested in preparing for labour using hypnosis when considering issues of timing and practice.

Although the interventions were clinically heterogeneous, we considered it reasonable to combine the studies as the interventions were considered to be sufficiently similar to produce meaningful results. Random-effects analysis was used when statistical heterogeneity was high, as planned and outlined in the methods section. Potential trial features which may account for the very substantial heterogeneity in this review were noted in the results. However, as single trials were often the source of the heterogeneity it was difficult to attribute this to any particular feature of the trial. Based on the current evidence, we cannot reliably identify the sources of most of the heterogeneity in this review.

## Quality of the evidence

The 'Risk of bias' figures (Figure 1; Figure 2) indicate that the risk of bias was moderate to high for all but one trial (Cyna 2011). Two of the trials (Harmon 1990; Rock 1969) were quasi-randomised trials so were at high risk of selection bias. Both of these trials found that women in the hypnosis group were less likely to use pharmacological pain relief compared with those in the control group. Only one trial (Cyna 2011) was rated as being at low risk of bias across all domains (except for blinding of participants for subjective measures which was attempted but was not successful). That trial did not find any significant differences between women in the hypnosis group and those in the control group. Previous analysis of studies comparing findings of trials with adequate allocation concealment and trials with inadequate or unclear concealment of allocation (including quasi-randomised trials) found no significant difference in four studies and larger estimates of effect in trials with inadequate allocation concealment in five studies (Odgaard-Jensen 2011). Overall, it was concluded that predictions could not be made about the likely magnitude or even the direction of possible selection biases for such studies (Odgaard-Jensen 2011).

Rates of follow-up were moderate to high, considering that the intervention was conducted antenatally in all but one trial (Rock 1969). Where losses to follow-up occurred, they generally did not appear to be related to the intervention. Blinding of participants was attempted in some studies (Cyna 2011; Harmon 1990; Martin 2001; Rock 1969) but only one study reported data on the success of this blinding (Cyna 2011). Given the difficulty of blinding participants to the intervention, risk of bias was assessed separately for subjective outcomes where lack of blinding may affect results (such as satisfaction with pain relief) and objective outcomes where lack

of blinding is not likely to affect results (such as spontaneous vaginal birth). It is not possible to blind the therapist who provides the hypnotic intervention but it is possible to blind medical personal who care for the woman during labour and outcome assessors for objective clinical outcomes. Three studies reported that outcome assessors were blinded to group allocation (Cyna 2011; Harmon 1990; Mehl-Madrona 2004) and medical personal were blinded in two studies (Cyna 2011; Martin 2001).

Most of the studies included in this review were small, with less than 100 participants in each trial arm (Fisher 2009; Freeman 1986; Harmon 1990; Martin 2001; Rock 1969). Recent research into the effect of small studies on meta-analyses of osteoarthritis trials found that small studies generally showed greater treatment effects than studies with at least 100 participants in each arm of the trial (Nuesch 2010), although it is not clear if this would apply more broadly.

There was a lack of consistency in the outcomes measured by the studies and there were several outcomes where information was only available from one study. This lack of data makes it difficult to fully assess any treatment effect from hypnosis for pain management for labour and birth. Authors of several studies were contacted to provide additional methodological information and results. The review includes all of the information obtained up to August 2012.

### Potential biases in the review process

We attempted to minimise bias during the review process by having two people assess the eligibility of studies, assess risk of bias and extract data with a third person involved to check or review each area. We attempted to be as inclusive as possible in our search.

### Agreements and disagreements with other studies or reviews

One other systematic review of hypnosis for pain management for labour and birth has been conducted (Cyna 2004). This review also updates an earlier Cochrane Review (Smith 2006) of complementary and alternative therapies for pain management in labour which included hypnosis. Both studies concluded that hypnosis may be beneficial for pain management in childbirth but noted that further large, high quality studies were needed as the number of women studied was small. Our findings are similar to these reviews although results from one additional large trial are included in this review.

## AUTHORS' CONCLUSIONS

### Implications for practice

There are still only a small number of studies assessing the use of hypnosis for labour and childbirth. Although hypnosis shows some promise, further high quality research is needed before recommendations can be made regarding its clinical usefulness for pain management in maternity care.

### Implications for research

Two large studies assessing hypnosis for pain management for labour and childbirth are currently underway ( ISRCTN27575146; NCT00914082). These appear to be adequately powered and include clinically relevant outcomes. There is a need to improve reporting in future trials so that accurate assessments of bias can be made (for example, more explicit explanation of randomisation processes). Reporting on the training and length of experience of the hypnotherapist may also be of value.

Evaluation of hypnosis interventions in institutions with and without an 'on demand' epidural service with a cost-benefit analysis to be incorporated into the design of future studies is recommended. It may also be useful for trialists to consider the timing and number of hypnosis sessions included in the intervention.

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# REFERENCES

## References to studies included in this review


**Cyna 2011** *{published and unpublished data}*

Cyna A. Hypnosis antenatal training for childbirth (HATCh): a randomised controlled trial (ongoing trial). ClinicalTrials.gov (http://www.clinicaltrials.gov/ct2/show/NCT00282204) (accessed January 13, 2011) 2006.

* Cyna AM. *The HATCh Trial: Hypnosis Antenatal Training for Childbirth (PhD thesis) (http://digital.library.adelaide.edu.au/dspace/bitstream/2440/69216/1/02whole.pdf)*. Adelaide, Austraila: The University of Adelaide, 2011.

Cyna AM, Andrew MI, Robinson JS, Crowther CA, Baghurst P, Turnbull D, et al.Hypnosis antenatal training for childbirth (HATCh): a randomised controlled trial. *BMC Pregnancy and Childbirth* 2006;**6**:5.

Cyna AM, Andrew MI, Whittle C. Hypnosis antenatal training for childbirth (HATCh): Intervention Scripts 1 and 4. *Australian Journal of Clinical and Experimental Hypnosis* 2007;**35**(1):83–94.

**Fisher 2009** *{published data only}*

Fisher B, Esplin S, Stoddard G, Silver R. Randomized controlled trial of hypnobirthing versus standard childbirth classes: patient satisfaction and attitudes towards labor. *American Journal of Obstetrics and Gynecology* 2009;**201**(6 Suppl 1):S61–S62.

**Freeman 1986** *{published data only}*

Freeman RM, Macaulay AJ, Eve L, Chamberlain GVP. Randomised trial of self hypnosis for analgesia in labour. *British Medical Journal* 1986;**292**:657–8.

**Harmon 1990** *{published data only}*

Harmon TAM. *Hypnotic analgesia in childbirth [PhD thesis]*. Milwaukee: The University of Wisconsin- Milwaukee, 1982.

* Harmon TM, Hynan MT, Tyre TE. Improved obstetric outcomes using hypnotic analgesia and skill mastery combined with childbirth education. *Journal of Consulting & Clinical Psychology* 1990;**58**:525–30.

**Martin 2001** *{published data only}*

Martin AA. *The effects of hypnosis and supportive counselling on the labor processes and birth outcomes of pregnant adolescents [PhD thesis]*. Gainesville: University of Florida, 1987.

* Martin AA, Schauble PG, Rai SH, Curry RW Jr. The effects of hypnosis on the labor processes and birth outcomes of pregnant adolescents. *Journal of Family Practice* 2001;**50**(5):441–3.

**Mehl-Madrona 2004** *{published data only}*

Mehl-Madrona LE. Hypnosis to facilitate uncomplicated birth. *American Journal of Clinical Hypnosis* 2004;**46**(4):299–312.

**Rock 1969** *{published data only}*

Rock NL, Shipley TE, Campbell C. Hypnosis with untrained, nonvolunteer patients in labor. *International Journal of Clinical and Experimental Hypnosis* 1969;**17**(1):25–36.


## References to studies excluded from this review


**Guse 2006** *{published data only}*

Guse T, Wissing M, Hartman W. The effect of a prenatal hypnotherapeutic programme on postnatal maternal psychological well-being. *Journal of Reproductive and Infant Psychology* 2006;**24**(2):163–77.


## References to studies awaiting assessment


**Hao 1997** *{published data only}*

Hao TY, Li YH, Yao SF. Clinical study on shortening the birth process using psychological suggestion therapy. *Zhonghua Hu Li Za Zhi* 1997;**32**(10):568–70.


## References to ongoing studies


**ISRCTN27575146** *{published data only}*

Downe S. The SHIP trial - a randomised controlled trial of self-hypnosis during labour. http://www.midirs.org/development/MIDIRSEssence.nsf/articles/F329431A7FF3E593802578A90052BFA5 (accessed 14 December 2011).

ISRCTN27575146. Self-Hypnosis for Intrapartum Pain management (SHIP) trial. http://isrctn.org/ISRCTN27575146 (accessed November 17, 2011).

**NCT00914082** *{published data only}*

NCT00914082. Mental training and childbirth. Current controlled trials (http://www.controlled-trials.com/mrct/trial/530499/hypnosis) (accessed January 13, 2011) 2009.


## Additional references


**Alexander 2009**

Alexander B, Turnbull D, Cyna A. The effect of pregnancy on hypnotizability. *American Journal of Clinical Hypnosis* 2009;**52**(1):13–22.

**AMA Council on Mental Health 1958**

American Medical Association Council on Mental Health. Hypnosis. *Journal of the American Medical Association* 1958;**168**(1):57.

**Anim-Somuah 2011**

Anim-Somuah M, Smyth RMD, Jones L. Epidural versus non-epidural or no analgesia in labour. *Cochrane Database of Systematic Reviews* 2011, Issue 12. [DOI: 10.1002/14651858.CD000331.pub3]

**Barber 1979**

Barber TX, Wilson SC. The Barber Suggestibility Scale and the Creative Imagination Scale: experimental and clinical applications. *American Journal of Clinical Hypnosis* 1979;**21**(2-3):84–108.

**Barragán 2011**

Barragán Loayza IM, Solà I, Juandó Prats C. Biofeedback for pain management during labour. *Cochrane Database*

*of Systematic Reviews* 2011, Issue 6. [DOI: 10.1002/14651858.CD006168.pub2]

**BMA Working Party 1955**
Psychological Medicine Group Committee of the British Medical Association. Medical use of hypnotism. *British Medical Journal* 1955;**1**(4920):190–3.

**Bonica 1990a**
Bonica JJ, editor. Definitions and taxonomy of pain. *The Management of Pain*. 2nd Edition. Malvern: Lea & Febiger, 1990:18–27.

**Bonica 1990b**
Bonica JJ, McDonald JS. The pain of childbirth. In: Bonica JJ editor(s). *The Management of Pain*. 2nd Edition. Malvern: Lea & Febiger, 1990:1313–43.

**BPS Working Party 2001**
British Psychological Society Working Party. *The nature of hypnosis. A report prepared by a Working Party at the request of The Professional Affairs Board ofThe British Psychological Society*. Leicester: British Psychological Society, 2001.

**Caton 2002**
Caton D, Corry MP, Frigoletto FD, Hopkins DP, Lieberman E, Mayberry L, et al.The nature and management of labor pain: executive summary. *American Journal of Obstetrics and Gynecology* 2002;**186**(5 Suppl 1):1–15.

**Chooi 2011**
Chooi CSL, Nerlekar R, Raju R, Cyna AM. The effects of positive or negative words when assessing postoperative pain. *Anaesthesia and Intensive Care* 2011;**39**(1):101–6.

**Cluett 2009**
Cluett ER, Burns E. Immersion in water in labour and birth. *Cochrane Database of Systematic Reviews* 2009, Issue 2. [DOI: 10.1002/14651858.CD000111.pub3]

**Cyna 2004**
Cyna AM, McAuliffe GL, Andrew MI. Hypnosis for pain relief in labour and childbirth: a systematic review. *British Journal of Anaesthesia* 2004;**93**(4):505–11.

**Derry 2012**
Derry S, Straube S, Moore RA, Hancock H, Collins SL. Intracutaneous or subcutaneous sterile water injection compared with blinded controls for pain management in labour. *Cochrane Database of Systematic Reviews* 2012, Issue 1. [DOI: 10.1002/14651858.CD009107.pub2]

**Dick-Read 1947**
Dick-Read G. *Childbirth Without Fear: The Principle and Practice of Natural Childbirth*. London: Heinemann Medical, 1947.

**Dowswell 2009**
Dowswell T, Bedwell C, Lavender T, Neilson JP. Transcutaneous electrical nerve stimulation (TENS) for pain management in labour. *Cochrane Database of Systematic Reviews* 2009, Issue 2. [DOI: 10.1002/14651858.CD007214.pub2]

**Egger 1997**
Egger M, Davey Smith G, Schneider M, Minder C. Bias in meta-analysis detected by a simple, graphical test. *BMJ* 1997;**315**(7109):629–34.

**Faymonville 2000**
Faymonville ME, Laureys S, Degueldre C, DelFiore G, Luxen A, Franck G, et al.Neural mechanisms of antinociceptive effects of hypnosis. *Anesthesiology* 2000;**92**(5):1257–67.

**Gamsa 2003**
Gamsa A. Hypnotic analgesia. In: Melzack R, Wall PD editor(s). *Handbook of Pain Management: A Clinical Companion to Wall and Melzack's Textbook of Pain*. Sydney: Churchill Livingstone, 2003:521–31.

**Gaskin 2003**
Gaskin IM. *Ina May's Guide to Childbirth*. New York: Bantam Dell, 2003.

**Green 1998**
Green J, Coupland V, Kitzinger J. *Great Expectations: A Prospective Study of Women's Expectations and Experiences of Childbirth*. 2nd Edition. Cheshire: Books for Midwives Press, 1998.

**Hallquist 2007**
Hallquist MN, Jensen MP, Patterson DR, Lynn SJ, Montgomery GH. Clinical hypnosis for acute pain in adults. *Cochrane Database of Systematic Reviews* 2007, Issue 3. [DOI: 10.1002/14651858.CD006599]

**Harbord 2006**
Harbord RM, Egger M, Sterne JA. A modified test for small-study effects in meta-analyses of controlled trials with binary endpoints. *Statistics in Medicine* 2006;**25**(20):3443–57.

**Higgins 2011**
Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions, Version 5.1.0 (updated March 2011). The Cochrane Collaboration 2011. Available from www.cochrane-handbook.org.

**Hodnett 2011**
Hodnett ED, Gates S, Hofmeyr GJ, Sakala C, Weston J. Continuous support for women during childbirth. *Cochrane Database of Systematic Reviews* 2011, Issue 2. [DOI: 10.1002/14651858.CD003766.pub3]

**Howell 2009**
Howell, M. *Effective Birth Preparation*. Headley Down: Intuition UN, 2009.

**Jones 2011**
Jones L, Dou L, Dowswell T, Alfirevic Z, Neilson JP. Pain management for women in labour: generic protocol. *Cochrane Database of Systematic Reviews* 2011, Issue 6. [DOI: 10.1002/14651858.CD009167]

**Jones 2012**
Jones L, Othman M, Dowswell T, Alfirevic Z, Gates S, Newburn M, et al.Pain management for women in labour: an overview of systematic reviews. *Cochrane Database of Systematic Reviews* 2012, Issue 3. [DOI: 10.1002/14651858.CD009234.pub2]

**Klomp 2011**
Klomp T, van PM, Lazet J, Di NM. Inhaled analgesia for pain management in labour. *Cochrane Database of Systematic Reviews* 2011, Issue 10. [DOI: 10.1002/14651858.CD009351]

**Kroger 1957**
Kroger WS, DeLee ST. Use of hypnoanesthesia for cesarean section and hysterectomy. *Journal of the American Medical Association* 1957;**163**(6):442–4. [DOI: 10.1001/jama.1957.82970410001009]

**Lawrence 2009**
Lawrence A, Lewis L, Hofmeyr GJ, Dowswell T, Styles C. Maternal positions and mobility during first stage labour. *Cochrane Database of Systematic Reviews* 2009, Issue 2. [DOI: 10.1002/14651858.CD003934.pub2]

**Lewis 1992**
Lewis DO. Hypnoanalgesia for chronic pain: the response to multiple inductions at one session and to separate single inductions. *Journal of the Royal Society of Medicine* 1992;**85**: 620–4.

**Lowe 1989**
Lowe NK. Explaining the pain of active labour: the importance of maternal confidence. *Research Nursing and Health* 1989;**12**(4):237–45.

**Lowe 2002**
Lowe NK. The nature of labor pain. *American Journal of Obstetrics and Gynecology* 2002;**186**(5 Suppl 1):16–24.

**Lundgren 1998**
Lundgren I, Dahlberg K. Women's experience of pain in childbirth. *Midwifery* 1998;**14**:105–10.

**Maquet 1999**
Maquet P, Faymonville ME, Degueldre C, Delfiore G, Luxen A, Franck G, et al.Functional neuroanatomy of hypnotic state. *Biological Psychiatry* 1999;**45**(3):327–33.

**McCutcheon-Rosegg 1996**
McCutcheon-Rosegg S, Ingraham E, Bradley RA. *Natural Childbirth the Bradley Way*. Revised. New York: Plume, 1996.

**McIntyre 2010**
McIntyre PE, Schug SA, Scott DA, Visser EJ, Walker SM, editors. *Acute Pain Management: Scientific Evidence*. 3rd Edition. Melbourne: ANZCA & FPM, 2010.

**Melzack 1984**
Melzack R, Kinch R, Dobkin P, Lebrun M, Taezner P. Severity of labour pain: influence of physical as well as psychologic variables. *Canadian Medical Association Journal* 1984;**130**(5):579–84.

**Mongan 2005**
Mongan MF. *HypnoBirthing: The Mongan Method*. 3rd Edition. Deerfield Beach: Health Communications, 2005.

**Montgomery 2000**
Montgomery GH, Duhamel KN, Redd WH. A meta-analysis of hypnotically induced analgesia: how effective is hypnosis?. *International Journal of Clinical and Experimental Hypnosis* 2000;**48**(2):138–53.

**Novikova 2012**
Novikova N, Cluver C. Local anaesthetic nerve block for pain management in labour. *Cochrane Database of Systematic Reviews* 2012, Issue 4. [DOI: 10.1002/14651858.CD009200.pub2]

**Nuesch 2010**
Nuesch E, Trelle S, Reichenback S, Rutjes AWS, Tschannen B, Altman DG, et al.Small study effects in meta-analyses of osteoarthritis trial: meta-epidemiological study. *BMJ* 2010; **341**:c3515. [DOI: 10.1136/bmj.c3515]

**Odgaard-Jensen 2011**
Odgaard-Jensen J, Vist GE, Timmer A, Kunz R, Akl EA, Schunemann H, et al.Randomisation to protect against selection bias in healthcare trials. *Cochrane Database of Systematic Reviews* 2011, Issue 4. [DOI: 10.1002/14651858.MR000012.pub3]

**Othman 2011**
Othman M, Jones L, Neilson JP. Non-opioid drugs for pain management in labour. *Cochrane Database of Systematic Reviews* 2011, Issue 7. [DOI: 10.1002/14651858.CD009223]

**Patterson 2003**
Patterson DR, Jensen, M. Hypnosis and clinical pain. *Psychological Bulletin* 2003;**129**(4):495–521.

**Platonov 1960**
Platonov K. Psychotherapeutic methods and their application in painless childbirth: Lectures for obstetricians. In: Nikolaev AP, Vel'vovskii IZ, Velvovsky I editor(s). *Painless Childbirth through Psychoprophylaxis*. Moscow: Foreign Languages Publication House, 1960.

**Rainville 1997**
Rainville P, Duncan GH, Price DD, Carrier B, Bushnell C. Pain affect encoded in human anterior cingulate but not somatosensory cortex. *Science* 1997;**277**:968–71. [DOI: 10.1126/science.277.5328.968]

**RevMan 2011**
The Nordic Cochrane Centre, The Cochrane Collaboration. Review Manager (RevMan). 5.1. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2011.

**Samko 1975**
Samko MR, Schoenfeld LS. Hypnotic susceptibility and the Lamaze childbirth experience. *American Journal of Obstetrcis and Gynecology* 1975;**121**:631–6.

**Simkin 2004**
Simkin P, Bolding A. Update on nonpharmacologic approaches to relieve labor pain and prevent suffering. *Journal of Midwifery & Women's Health* 2004;**49**(6): 489–504. [PUBMED: 15544978]

**Simmons 2007**
Simmons SW, Cyna AM, Dennis AT, Hughes D. Combined spinal-epidural versus epidural analgesia in labour. *Cochrane Database of Systematic Reviews* 2007, Issue 3. [DOI: 10.1002/14651858.CD003401.pub2]

**Smith 2006**
Smith CA, Collins CT, Cyna AM, Crowther CA. Complementary and alternative therapies for pain management in labour. *Cochrane Database of Systematic Reviews* 2006, Issue 4. [DOI: 10.1002/14651858.CD003521.pub2]

**Smith 2011a**
Smith CA, Collins CT, Crowther CA. Aromatherapy for pain management in labour. *Cochrane Database of Systematic Reviews* 2011, Issue 7. [DOI: 10.1002/14651858.CD009215]

**Smith 2011b**
Smith CA, Collins CT, Crowther CA, Levett KM. Acupuncture or acupressure for pain management in labour. *Cochrane Database of Systematic Reviews* 2011, Issue 7. [DOI: 10.1002/14651858.CD009232]

**Smith 2011c**
Smith CA, Levett KM, Collins CT, Crowther CA. Relaxation techniques for pain management in labour. *Cochrane Database of Systematic Reviews* 2011, Issue 12. [DOI: 10.1002/14651858.CD009514]

**Smith 2012**
Smith CA, Levett KM, Collins CT, Jones L. Massage, reflexology and other manual methods for pain management in labour. *Cochrane Database of Systematic Reviews* 2012, Issue 2. [DOI: 10.1002/14651858.CD009290.pub2]

**Stam 1984**
Stam HJ, McGrath PA, Brooke RI. The effects of a cognitive-behavioral treatment program on temporo-mandibular pain and dysfunction syndrome. *Psychosomatic Medicine* 1984;**46**(6):534–45.

**Trentin 2001**
Trentin L, Visentin M, De Marco R, Zanolin E. Prevalence of pain in a public hospital: correlation between patients and caregivers. *Journal of Headache and Pain* 2001;**2**(2): 73–8. [DOI: 10.1007/PL00012189]

**Ullman 2010**
Ullman R, Smith LA, Burns E, Mori R, Dowswell T. Parenteral opioids for maternal pain management in labour. *Cochrane Database of Systematic Reviews* 2010, Issue 9. [DOI: 10.1002/14651858.CD007396.pub2]

* *Indicates the major publication for the study*

## CHARACTERISTICS OF STUDIES

### Characteristics of included studies *[ordered by study ID]*

**Cyna 2011**

| | |
|---|---|
| Methods | Randomised controlled trial of parallel design conducted in Women's and Children's Hospital, Adelaide, Australia |
| Participants | Inclusion criteria: women > 34 and < 39 weeks' gestation, with a singleton, viable fetus, vertex presentation, who are not in active labour and who are planning a vaginal birth<br>Exclusion criteria: previous hypnosis preparation for childbirth; poor understanding of English requiring a translator; women who are already enrolled in another pregnancy trial where analgesia requirements are an outcome measure; active psychological or psychiatric problems such as: active depression requiring treatment by a psychiatrist; schizophrenia; prior psychosis; severe intellectual disability. Also women with pain caused by specific pathological entities such as: congenital neuromuscular disorders; spina bifida; metastatic disease; osteoporosis; rheumatoid arthritis; fractures |
| Interventions | Intervention Group 1 (n = 154): antenatal hypnosis training in preparation for childbirth administered by a qualified hypnotherapist with the use of audio compact discs on hypnosis for re-enforcement<br>Intervention Group 2 (n = 143): antenatal hypnosis training in preparation for childbirth using audio compact discs on hypnosis administered by a nurse with no training in hypnotherapy<br>Controls (n = 151): participants continue with their usual preparation for childbirth with no additional intervention (no treatment)<br>The hypnosis interventions were provided in 3 sessions to groups of up to 10 women. The sessions commenced as closely as possible to 37 weeks' gestation |
| Outcomes | Use of pharmacological analgesia (nitrous oxide; opioids; epidural); use of oxytocics; mode of delivery; Apgar score less than seven at five minutes; admission to HDU/ICU; adverse effects for women (PPH => 600 mlL blood transfusion; death; ICU admission); adverse effects for infants (meconium-stained liquor; admission to neonatal unit); overall experience of pain during labour and childbirth - birth experience was worse/better, same as expected; whether birth rated as positive or negative experience; how well coped with labour/childbirth (postpartum questionnaire); length of labour; length of neonatal nursery stay; length of maternal stay; number women breastfeeding at discharge, 6-week and 6-month follow-up; Edinburgh Postnatal Depression Scale and Spielberger anxiety scales repeated at 6 weeks and 6 months. Hypnotisability was also measured using the Creative Imagination Scale (CIS) with high hypnotisability defined as a score greater than or equal to 23 and low hypnotisability defined as a score < 23 |
| Notes | Principal investigator contacted on 19/8/2011 and replied " The Cyna trial is complete and it has been written up and accepted in part as a PhD thesis. We are currently preparing the paper for submission to a journal". Update January 2012 - the digital thesis is now available online. The principal investigator has also provided additional data and information about methodology as requested |
| ***Risk of bias*** | |

| Bias | Authors' judgement | Support for judgement |
|---|---|---|
| Random sequence generation (selection bias) | Low risk | "computer-generated random number sequence." The author provided additional detail that "Study participants were stratified for parity and randomised in (unspecified) blocks of 15 by a computer random number generator." |
| Allocation concealment (selection bias) | Low risk | "we were provided with group allocation via telephone at the Department of Public Health for the first 6 months of the study and then by a password-protected computer database program."<br>"The randomization sequence was inaccessible to research assistants involved in recruiting potential trial participants." The author provided additional detail that "Allocation concealment was assured by using a computer database assignment to one of three groups, which was only revealed after patient identifiers had been entered." |
| Blinding of participants (objective outcomes) | Low risk | Participant: "All participants were informed that they may or may not appreciate which group they are in, as we believed that some women might think that the baseline testing for hypnotisability was the intervention. However, we did expect that most women allocated to usual care would probably realise they were not in an intervention group. An assessment of blinding was determined by asking participants if they thought they were in a control or intervention group in the final post-partum questionnaire." 110 of 134 in the hypnosis believed they were in the hypnosis arm of the trial, 98 of 133 women in the CD believed they were in the hypnosis and 0 of 133 of women in the control of the trial believed they were in the hypnosis. High risk of bias for subjective outcomes (such as satisfaction with pain relief) and low risk of bias for objective outcomes (such as spontaneous vaginal birth) |
| Blinding of participants (subjective outcomes) | High risk | Participant: "All participants were informed that they may or may not appreciate |

| | | |
|---|---|---|
| | | which group they are in, as we believed that some women might think that the baseline testing for hypnotisability was the intervention. However, we did expect that most women allocated to usual care would probably realise they were not in an intervention group. An assessment of blinding was determined by asking participants if they thought they were in a control or intervention group in the final post-partum questionnaire." 110 of 134 in the hypnosis group believed they were in the hypnosis arm of the trial, 98 of 133 women in the CD arm believed they were in the hypnosis arm and 0 of 133 of women in the control arm of the trial believed they were in the hypnosis arm. High risk of bias for subjective outcomes (such as satisfaction with pain relief) and low risk of bias for objective outcomes (such as spontaneous vaginal birth) |
| Blinding of personnel (performance bias) | Low risk | Clinician: confirmed with the author that clinicians caring for the women in labour were blinded to group allocation. |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Low risk | "All data were collected and analysed by researchers who were unaware of the participants' group allocation." |
| Incomplete outcome data (attrition bias)<br>All outcomes | Low risk | 190 women not randomised, (50 declined to participate and 140 did not meet eligibility criteria) 137 were excluded after randomisation due to protocol violations (see below). All other women analysed at birth. 48 women lost to follow-up at 6 week follow-up (live hypnosis group = 20, audio CD hypnosis group = 10, control group = 18).<br>138 women were excluded due to protocol violations 1 in active labour, 137 gestation less than or equal to 34 weeks at randomisation due to human error at the point of randomisation. The author provided additional detail that "After completing nearly two years of recruitment, we became aware that some women, who were ineligible for participation, had been in- |

**Cyna 2011** (*Continued*)

| | | |
|---|---|---|
| | | advertently randomized, outside our eligibility criteria, prior to 34 weeks gestation. We therefore planned to continue to recruit women to the study until our initial planned sample size of eligible women had been reached. Only those women who met all eligibility criteria for inclusion were analysed."<br>All primary and secondary outcomes of trial participants fulfilling all eligibility criteria were analysed using the 'Intention-to-treat' principle |
| Selective reporting (reporting bias) | Low risk | All outcomes listed in trial registration reported except maternal rating of control during labour and breastfeeding rates at discharge from hospital (and breastfeeding at 6 months) - data provided by the author<br>Additional secondary outcomes not listed in trial registration also reported |
| Other bias | Low risk | "Our analyses of baseline data shows that the randomisation with stratification for parity produced comparable groups with the exception of the incidence of women with a history of depression, and an EPDS score > 12 being increased in the Hypnosis Group. The distribution of all other participants' baseline demographic data across the three groups, such as mothers' use of complementary therapies during their pregnancy, age, weight and country of birth, were also comparable." |

**Fisher 2009**

| | |
|---|---|
| Methods | Randomised controlled trial conducted in a USA hospital setting |
| Participants | 38 women participated in this trial, 17 in the intervention group and 21 in the control group. Inclusion criteria: patients being interested in childbirth preparatory courses |
| Interventions | Intervention group received hypnobirthing while the control group received standard childbirth preparation course |
| Outcomes | Ability to cope; route of delivery; caesarean section; Apgar score; intrapartum and postpartum epidural and analgesic use |

**Fisher 2009** (*Continued*)

| | |
|---|---|
| Notes | This is an abstract of poster presentation and so information was very limited. Principal investigator contacted on 17/1/12 seeking further information about methodology and outcome data |

***Risk of bias***

| Bias | Authors' judgement | Support for judgement |
|---|---|---|
| Random sequence generation (selection bias) | Unclear risk | Described as randomised - no further details. |
| Allocation concealment (selection bias) | Unclear risk | Not described. |
| Blinding of participants (objective outcomes) | Unclear risk | Not reported. |
| Blinding of participants (subjective outcomes) | Unclear risk | Not reported. |
| Blinding of personnel (performance bias) | Unclear risk | Not reported. |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Unclear risk | Not reported. |
| Incomplete outcome data (attrition bias)<br>All outcomes | Unclear risk | Not reported. |
| Selective reporting (reporting bias) | Unclear risk | Only an abstract and so word limit on reporting of data - no numerical data reported |
| Other bias | Low risk | The 2 groups were comparable. |

**Freeman 1986**

| | |
|---|---|
| Methods | Randomised controlled trial conducted in St George's Hospital Medical School, London, UK |
| Participants | 65 women participated in this trial, 29 in the intervention group and 36 in the control group. Inclusion criteria: normal pregnancy and a desire to avoid epidural anaesthesia |
| Interventions | In the intervention group women attended routine weekly antenatal classes. They were also seen individually every week from 32 weeks' gestation where they received hypnosis regarding relaxation and pain relief. Patients were encouraged to imagine warmth or anaesthesia in 1 hand and shown how to transfer this to the abdomen<br>In the control group women attended routine weekly antenatal classes |

**Freeman 1986** (*Continued*)

| | |
|---|---|
| Outcomes | Pain intensity (linear analogue scale); satisfaction with childbirth experience ("very satisfied" with labour (score 8-10 on linear analogue scale); assisted vaginal birth; use of additional analgesia (epidural, pethidine); spontaneous vaginal birth; length of labour |
| Notes | |

***Risk of bias***

| Bias | Authors' judgement | Support for judgement |
|---|---|---|
| Random sequence generation (selection bias) | Unclear risk | Randomly assigned - no other detail. |
| Allocation concealment (selection bias) | Unclear risk | Not reported. |
| Blinding of participants (objective outcomes) | Unclear risk | Not reported. |
| Blinding of participants (subjective outcomes) | Unclear risk | Not reported. |
| Blinding of personnel (performance bias) | Unclear risk | Not reported. |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Unclear risk | Not reported. |
| Incomplete outcome data (attrition bias)<br>All outcomes | High risk | 17 excluded after randomisation due to: pre-eclampsia (1), breech presentation (3) , caesarean section (9), failed to attend for hypnosis (4) |
| Selective reporting (reporting bias) | Unclear risk | Did not report pain efficacy data - but short report so limit on reporting of data. |
| Other bias | Unclear risk | No baseline characteristics table. |

**Harmon 1990**

| | |
|---|---|
| Methods | Quasi-randomised controlled trial conducted in a USA hospital setting |
| Participants | 60 women participated in this trial, 30 in each arm. Inclusion criteria: women ranging in age from 18 to 35 years, nulliparous, married, white, during the end of the second trimester of pregnancy. No reported history of (1) psychiatric hospitalisation, (2) depression during pregnancy, or (3) obstetric risk (e.g. miscarriage, pre-eclampsia, diabetes, etc. ). The study did accept women with borderline hypertension |

**Harmon 1990** (*Continued*)

| | |
|---|---|
| Interventions | Experimental group: antenatal preparation was conducted over 6 1-hour weekly sessions. Participants in the hypnosis group heard the live hypnotic induction during Session 1 and heard the taped induction at the beginning of Sessions 2-6. Women were then given 2 trials of an IPT using the dominant arm. Women were also given a cassette tape recording of the hypnotic induction and told to practice daily<br>Control group: antenatal preparation was conducted over 6 1-hour weekly sessions. Control participants listened to the control tape at the beginning of each treatment session. Women were then given 2 trials of the same IPT. Women were given a cassette tape recording of 'Practice for Childbirth' and told to practice daily<br>Antenatal preparation began "in the early portion of the third trimester" and the sessions included up to 15 women<br>Both groups attended 6 childbirth education classes provided by their physicians |
| Outcomes | Pain intensity (measured on the McGill Pain Questionaire Present Pain Intensity Scale where 0 = No pain, 1 = Mild, 2 = Discomforting, 3 = Distressing, 4 = Horrible, 5 = Excruciating); postnatal depressive symptoms (Depression scores on Minnesoto Mulitphasic Personality Inventory (MMPI) Depression Scale); Apgar score < 7 at 5 minutes; length of labour; spontaneous vaginal birth; use of pharmacological pain relief; caesarean section. Hypnotisability was also measured using the Harvard Group Scale of Hypnotic Susceptibility. High hypnotisability was defined as a score greater than or equal to 7 and low hypnotisability was defined as a score < 7 |
| Notes | |

***Risk of bias***

| **Bias** | **Authors' judgement** | **Support for judgement** |
|---|---|---|
| Random sequence generation (selection bias) | High risk | Quasi-randomised controlled trial - "Assignment to one of the two treatment groups (hypnosis or control) was based solely on the month the woman was expected to deliver" |
| Allocation concealment (selection bias) | High risk | Quasi-randomised controlled trial - "Assignment to one of the two treatment groups (hypnosis or control) was based solely on the month the woman was expected to deliver" |
| Blinding of participants (objective outcomes) | Low risk | "Subjects were not informed that there were two treatment conditions; all were told that they would be receiving additional specialized childbirth training." |
| Blinding of participants (subjective outcomes) | Unclear risk | Women not told their group allocation but there was no reporting about whether blinding was successful |

**Harmon 1990** (*Continued*)

| | | |
|---|---|---|
| Blinding of personnel (performance bias) | Unclear risk | Not reported. |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Low risk | "blind ratings" noted as part of discussion of shortcomings of previous studies where the outcomes were not blinded |
| Incomplete outcome data (attrition bias)<br>All outcomes | Low risk | 3 women excluded because each had 1 or more pre-treatment scores > 70 on the MMPI and 1 woman excluded due to caesarean section |
| Selective reporting (reporting bias) | Low risk | All prespecified outcomes reported upon. |
| Other bias | Unclear risk | No baseline demographic characteristics table presented. |

**Martin 2001**

| | |
|---|---|
| Methods | Randomised controlled trial conducted in Alachua County Public Health Unit, Gainseville Florida, USA |
| Participants | 42 women participated in this trial 22 in the intervention group and 20 in the control group. Inclusion criteria: teenage patients (18 years or younger at the time of conception) before the end of their 24th week of pregnancy |
| Interventions | Experimental group received childbirth preparation in self-hypnosis that incorporated information on labour and delivery<br>Control group received supportive counselling designed to control for interpersonal contact and social support and to provide an opportunity for discussion about pregnancy issues of concern to the patient<br>A retrospective comparison group of 24 women who received no specialised training was included in the study but has not been considered as part of this review as the women were not randomly assigned to the comparison group<br>The intervention was a 4-session sequence provided to women on a 1-to-1 basis |
| Outcomes | Caesarean section; spontaneous vaginal birth; assisted vaginal birth; admission to SCBU/NICU; number of maternal days in hospital after the birth; use of pharmacological pain relief, induction or augmentation with Pitocin |
| Notes | Information requested: email sent to authors requesting additional information on methods and clarification on definitions for outcomes (types of surgical intervention; complications; reason for hospital stay). No response to date but a copy of the PhD thesis reporting on the study has been obtained |

***Risk of bias***

| **Bias** | **Authors' judgement** | **Support for judgement** |
|---|---|---|

| | | |
|---|---|---|
| Random sequence generation (selection bias) | Unclear risk | "randomly assigned" |
| Allocation concealment (selection bias) | Unclear risk | Not reported. |
| Blinding of participants (objective outcomes) | Low risk | "Both groups of patients received the standard prenatal treatment protocol from the medical staff, nurse practitioners, and hospital staff, all of whom were blind to group assignment." |
| Blinding of participants (subjective outcomes) | Unclear risk | Women not told their group allocation but there was no reporting about whether blinding was successful |
| Blinding of personnel (performance bias) | Low risk | "Both groups of patients received the standard prenatal treatment protocol from the medical staff, nurse practitioners, and hospital staff, all of whom were blind to group assignment." |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Unclear risk | Complications and other data "were entered in subjects' records by obstetric staff who were unaware of the study."..."Statistical analysis was based on a simple count of the presence or absence of complications in the medical record by researchers (the researchers were not blinded to the patient's study assignment)" not clear who made outcome assessment |
| Incomplete outcome data (attrition bias)<br>All outcomes | Low risk | 5 participants chose not to participate in the study prior to randomisation. Following randomisation there was a loss of 5 participants (3 moved out of the area before the birth and 1 from each group did not complete the research protocol) - losses seem fairly balanced between groups and not likely to be related to the intervention |
| Selective reporting (reporting bias) | Low risk | All prespecified outcomes reported upon. |
| Other bias | Low risk | There were no statistically significant differences between the groups for racial group and relationship status, the groups were also comparable for age, educational background and parity |

**Mehl-Madrona 2004**

| | |
|---|---|
| Methods | Randomised study conducted in 3 locations: San Francisco, California; Tucson, Arizona; and Burlington, Vermont, USA. 10 years were required to recruit and treat 520 women (because of the limitations of how many patients could be treated at one time for free) |
| Participants | 520 women participated in this study. The number of participants in each arm of the study was not reported although subsequently confirmed by the author as 260 in each group. Exclusion criteria: women in the third trimester of pregnancy, pregnant women with diagnosed high-risk conditions, pregnant women with a DSM-IV psychiatric diagnosis |
| Interventions | Hypnosis group: hypnosis sessions 1-to-1 with the author.<br>Control group: further discussion of issues that arose during the assessment (supportive psychotherapy) 1-to-1 with the author's graduate psychology intern<br>A 'matched' comparison group, which received no specialised treatment, was included in the study but has not been considered as part of this review as the women were not randomly assigned<br>Women could attend for hypnotherapy or supportive psychotherapy as often as desired (subject to therapist availability) |
| Outcomes | Caesarean section; maternal side effects (complicated birth); newborn resuscitation; epidural use; use of pharmacological pain relief; maternal depression; low Apgar scores; primary PPH; labour induction or augmentation with oxytocin |
| Notes | Information requested: email sent to author requesting additional information on methods and number of participants in each arm. Response received by AMC in 2006 and 2012 |

***Risk of bias***

| **Bias** | **Authors' judgement** | **Support for judgement** |
|---|---|---|
| Random sequence generation (selection bias) | Low risk | Random number generator. |
| Allocation concealment (selection bias) | Unclear risk | Not reported. |
| Blinding of participants (objective outcomes) | Unclear risk | Not reported. |
| Blinding of participants (subjective outcomes) | Unclear risk | Not reported. |
| Blinding of personnel (performance bias) | Unclear risk | Not reported. |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Low risk | An obstetrician and 2 midwives who were blind to the existence of the study reviewed each case to assess outcome variables |

**Mehl-Madrona 2004** (*Continued*)

| | | |
|---|---|---|
| Incomplete outcome data (attrition bias) All outcomes | High risk | "19 subjects refused hypnosis, but were included in the hypnosis group anyway, under an intention to treat design....Ninety-nine subjects declined an additional interview with the graduate intern... Once hypnosis was underway the author excluded from data analysis any patient who he came to diagnose with an anxiety disorder, major depressive disorder, specific axis II personality disorder (axis II traits were acceptable) , a psychotic disorder, dysthymic disorder, cyclothymia, or other major affective disorder." No details were reported regarding the number of women who were excluded from the hypnosis and control groups |
| Selective reporting (reporting bias) | High risk | Apgar score and PPH not reported upon. Induction and augmentation with oxytocin not reported numerically |
| Other bias | Unclear risk | No baseline characteristics. |

**Rock 1969**

| | |
|---|---|
| Methods | Single-centre quasi-randomised controlled trial at Temple University Obstetrical Servlce, Philadelphia, Pennsylvania, USA |
| Participants | 40 women in labour "Patients were selected from the wards of the Temple University Obstetrical Service, and they were selected by the following criteria: a) the patients were believed to be at term; b) as far as could be ascertained, no obstetrical or other abnormalities existed; c) the patients were believed to be in labour; and d) labour had not progressed beyond 4 cm of cervical dilation |
| Interventions | Hypnosis group: hypnosis with suggestions for comfort, relaxation and anaesthesia provided by a medical student who sat by the woman. The medical student also undertook routine medical observations and examinations<br>Control: a medical student sat by the woman and undertook routine medical observations and examinations (usual care) |
| Outcomes | Use of pharmacological analgesia, pain intensity, use of epidural/neuroaxial block as additional analgesia, postnatal depressive symptoms |
| Notes | |

***Risk of bias***

| **Bias** | **Authors' judgement** | **Support for judgement** |
|---|---|---|

**Rock 1969** (*Continued*)

| | | |
|---|---|---|
| Random sequence generation (selection bias) | High risk | Quasi-randomised controlled trial - "the patient was assigned, at any hour of the day or night, to either the experimental (hypnotic) or control group if she met the criteria for the study. If the last digit of the hospital history number was odd, the patient was assigned to the experimental group; if the digit was even, the patient was assigned to the control group." |
| Allocation concealment (selection bias) | High risk | Quasi-randomised controlled trial with an attempt to conceal allocation "in order to eliminate any bias in assigning patients to either the experimental or the control group, history number was concealed until after the patient had been examined and the decision had been made that she met all the criteria for the study." |
| Blinding of participants (objective outcomes) | Low risk | "After the patient was assigned to the experimental group, the hypnotist began the procedure by telling her that he would help her with her labour. The patient was not told that she was to be hypnotized; she was not asked if she wished to be helped." |
| Blinding of participants (subjective outcomes) | Unclear risk | Women not told their group allocation but there was no reporting about whether blinding was successful |
| Blinding of personnel (performance bias) | High risk | The hypnosis intervention was provided by main care provider for labour so high risk of bias |
| Blinding of outcome assessment (detection bias)<br>All outcomes | Unclear risk | Some outcomes were assessed by the hypnotist, some by a resident and postpartum outcomes were assessed by a co-author who had not been present in the labour room and who was not previously known to the woman. Unclear if the resident and/or co-authors were blind to women's group allocation |
| Incomplete outcome data (attrition bias)<br>All outcomes | Low risk | Intervention was provided during labour and no losses were noted |
| Selective reporting (reporting bias) | Unclear risk | Results mainly reported in the narrative and only tabulated for the experimental group. Only reports results for pain as a P |

**Rock 1969** (*Continued*)

| | | |
|---|---|---|
| | | value "patients in the experimental group rated their experience as less painful" (P < 0.01) |
| Other bias | Unclear risk | Baseline characteristics for patients not presented - narrative report on groups being comparable for ages, despite differences in parity - no other detail |

DSM-IV: Diagnostic and Statistical Manual of Mental Disorders 4th edition
EPDS: Edinburgh Postnatal Depression Scale
HDU: high dependency unit
ICU: intensive care unit
IPT: Ischemic Pain Task
PPH: postpartum haemorrhage

## Characteristics of excluded studies *[ordered by study ID]*

| Study | Reason for exclusion |
|---|---|
| Guse 2006 | Intervention not for pain management during labour and childbirth |

## Characteristics of studies awaiting assessment *[ordered by study ID]*

**Hao 1997**

| | |
|---|---|
| Methods | Randomised controlled trial. |
| Participants | 120 healthy, full-term primiparous women with singleton pregnancy and cephalic presentation |
| Interventions | "psychological suggestion" ('insubstantial comfort'). |
| Outcomes | Length of labour. |
| Notes | Taken from the abstract, full article in Chinese. |

## Characteristics of ongoing studies *[ordered by study ID]*

**ISRCTN27575146**

| | |
|---|---|
| Trial name or title | Self-Hypnosis for Intrapartum Pain management (SHIP) trial. |
| Methods | Multicentre pragmatic exploratory non-blinded randomised controlled trial |
| Participants | Inclusion criteria: all nulliparous women who: 1. Have a singleton, viable, cephalic pregnancy 2. Are planning a vaginal birth in hospital 3. Have no current history of being under treatment for psychiatric disorders or of hypertensive disorders 4. Speak and read English 5. Consent to take part 6. Who are available to attend the intervention sessions 7. Aged between 18 and 45 years, |
| Interventions | Intervention group: 2 antenatal group hypnosis sessions at 32 and 35 weeks' gestation with trained midwives. Participants will also be asked to listen to a CD of reinforcement exercises at least once a day until their baby is born<br>Control group: 'usual care' will consist of attendance at any antenatal classes usually offered to nulliparous women, and standard clinical care |
| Outcomes | Rates of epidural usage in labour for maternal request; mode of birth and other maternal labour outcomes; neonatal well-being; participants preferences relating to hypnosis; anxiety and fear about labour; recall of labour pain; ability to manage labour; satisfaction with self during labour; clinical and psychological morbidity and well-being; economic cost-benefit analysis; experiences of women, their birth companions, and their caregivers |
| Starting date | August 1, 2010. |
| Contact information | Email: sdowne@uclan.ac.uk Telephone: +44 (0)1772 893815 |
| Notes | |

**NCT00914082**

| | |
|---|---|
| Trial name or title | Mental Training and Childbirth. |
| Methods | Randomised trial using 3-arm group design conducted in Aarhus University Hospital, University of Aarhus, Denmark |
| Participants | Inclusion criteria: singleton pregnancy; nulliparous; planning a normal vaginal delivery<br>Exclusion criteria: poor understanding of Danish; psychological and psychiatric problems; medical disorders |
| Interventions | Intervention group: 3 antenatal classes in self-hypnosis taught by midwives with qualified training in hypnosis. The course includes audio compact discs for homework in self-hypnosis<br>Comparator group: 3 antenatal classes. The program is taught by the same midwives as in the intervention group and includes a mixture of training in different relaxation methods and mindfulness. This course also includes audio compact discs for homework<br>Control group: ordinary antenatal care and no additional interventions |
| Outcomes | Birth experience (pain, control, anxiety); medical intervention including mode of delivery; haemorrhage during birth; infection during birth and first 6 weeks postpartum (mother and child); postnatal depression; |

**NCT00914082** (*Continued*)

| | |
|---|---|
| | breastfeeding duration; child's condition and well-being at birth and 6 months later |
| Starting date | April 2009. |
| Contact information | Email: anette.werner@soci.au.dk Telephone: +45 40195755<br>Email: uldbjerg@ki.au.dk Telephone: +45 89496315 |
| Notes | Authors contacted by AMC. Trial completed and being prepared for publication - January 2012 |

## DATA AND ANALYSES

### Comparison 1. Self-hypnosis or hypnotherapy versus control

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Use of pharmacological pain relief/anaesthesia | 6 | 1032 | Risk Ratio (M-H, Random, 95% CI) | 0.63 [0.39, 1.01] |
| 1.1 1st and 2nd trimester | 1 | 520 | Risk Ratio (M-H, Random, 95% CI) | 0.42 [0.33, 0.52] |
| 1.2 2nd trimester | 1 | 42 | Risk Ratio (M-H, Random, 95% CI) | 0.65 [0.38, 1.11] |
| 1.3 3rd trimester | 4 | 470 | Risk Ratio (M-H, Random, 95% CI) | 0.78 [0.55, 1.12] |
| 2 Satisfaction with pain relief | 1 | 264 | Risk Ratio (M-H, Fixed, 95% CI) | 1.06 [0.94, 1.20] |
| 3 Spontaneous vaginal birth | 4 | 472 | Risk Ratio (M-H, Random, 95% CI) | 1.35 [0.93, 1.96] |
| 3.1 2nd trimester | 1 | 42 | Risk Ratio (M-H, Random, 95% CI) | 2.42 [1.43, 4.07] |
| 3.2 3rd trimester | 3 | 430 | Risk Ratio (M-H, Random, 95% CI) | 1.16 [0.85, 1.57] |
| 4 Pain intensity (scale 0 no pain; 5 excruciating) | 1 | 60 | Mean Difference (IV, Fixed, 95% CI) | -0.70 [-1.03, -0.37] |
| 5 Satisfaction with childbirth experience | 2 | 370 | Risk Ratio (M-H, Random, 95% CI) | 1.36 [0.52, 3.59] |
| 6 Breastfeeding at discharge (any) | 1 | 304 | Risk Ratio (M-H, Fixed, 95% CI) | 1.00 [0.97, 1.03] |
| 7 Assisted vaginal birth | 4 | 474 | Risk Ratio (M-H, Random, 95% CI) | 0.61 [0.32, 1.15] |
| 8 Caesarean section | 3 | 867 | Risk Ratio (M-H, Random, 95% CI) | 0.58 [0.20, 1.65] |
| 9 Admission to neonatal intensive care unit | 2 | 347 | Risk Ratio (M-H, Random, 95% CI) | 0.58 [0.12, 2.89] |
| 10 Apgar score less than 7 at 5 minutes | 2 | 365 | Risk Ratio (M-H, Random, 95% CI) | 0.49 [0.04, 5.35] |
| 11 Use of epidural/neuroaxial block | 4 | 930 | Risk Ratio (M-H, Random, 95% CI) | 0.76 [0.29, 2.02] |
| 12 Length of labour from 5 cm dilation to birth (minutes) | 1 | 60 | Mean Difference (IV, Fixed, 95% CI) | -165.2 [-223.53, -106.87] |
| 13 Induction of labour | 2 | 365 | Risk Ratio (M-H, Random, 95% CI) | 0.80 [0.26, 2.46] |
| 14 Augmentation of labour | 1 | 305 | Risk Ratio (M-H, Fixed, 95% CI) | 0.98 [0.76, 1.27] |
| 15 Primary postpartum haemorrhage (> 500 mL) | 1 | 305 | Risk Ratio (M-H, Fixed, 95% CI) | 1.68 [0.90, 3.12] |
| 16 Need for postpartum blood transfusion | 1 | 305 | Risk Ratio (M-H, Fixed, 95% CI) | 3.92 [0.44, 34.69] |
| 17 Postnatal depression | 2 | 345 | Risk Ratio (M-H, Random, 95% CI) | 1.17 [0.77, 1.78] |
| 18 Number of maternal days in hospital after birth (> 2 days) | 1 | 42 | Risk Ratio (M-H, Fixed, 95% CI) | 0.11 [0.02, 0.83] |
| 19 Other adverse events - newborn resuscitation | 1 | 520 | Risk Ratio (M-H, Fixed, 95% CI) | 0.67 [0.11, 3.96] |
| 20 Other adverse events - women readmitted to hospital | 1 | 267 | Risk Ratio (M-H, Fixed, 95% CI) | 1.56 [0.62, 3.90] |
| 21 Other adverse events - infants readmitted to hospital | 1 | 267 | Risk Ratio (M-H, Fixed, 95% CI) | 1.39 [0.64, 3.02] |
| 22 Other adverse events - maternal admission to HDU/ICU | 1 | 305 | Risk Ratio (M-H, Fixed, 95% CI) | 1.47 [0.25, 8.68] |

**Comparison 2. Nurse/CD hypnosis versus control**

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Use of pharmacological pain relief/anaesthesia | 1 | 294 | Risk Ratio (M-H, Fixed, 95% CI) | 1.01 [0.89, 1.15] |
| 2 Satisfaction with pain relief | 1 | 259 | Risk Ratio (M-H, Fixed, 95% CI) | 0.91 [0.78, 1.05] |
| 3 Spontaneous vaginal birth | 1 | 294 | Risk Ratio (M-H, Fixed, 95% CI) | 0.96 [0.80, 1.16] |
| 4 Satisfaction with childbirth experience | 1 | 294 | Risk Ratio (M-H, Fixed, 95% CI) | 0.94 [0.83, 1.07] |
| 5 Breastfeeding at discharge | 1 | 294 | Risk Ratio (M-H, Fixed, 95% CI) | 1.01 [0.98, 1.04] |
| 6 Assisted vaginal birth | 1 | 294 | Risk Ratio (M-H, Fixed, 95% CI) | 1.20 [0.78, 1.85] |
| 7 Caesarean section | 1 | 294 | Risk Ratio (M-H, Fixed, 95% CI) | 0.91 [0.56, 1.48] |
| 8 Admission to neonatal intensive care unit | 1 | 294 | Risk Ratio (M-H, Fixed, 95% CI) | 0.93 [0.67, 1.29] |
| 9 Apgar score less than 7 at 5 minutes | 1 | 294 | Risk Ratio (M-H, Fixed, 95% CI) | 0.53 [0.05, 5.76] |
| 10 Use of epidural/neuroaxial block | 1 | 294 | Risk Ratio (M-H, Random, 95% CI) | 0.94 [0.73, 1.20] |
| 11 Induction of labour | 1 | 294 | Risk Ratio (M-H, Fixed, 95% CI) | 0.97 [0.68, 1.36] |
| 12 Augmentation of labour | 1 | 294 | Risk Ratio (M-H, Fixed, 95% CI) | 1.06 [0.82, 1.36] |
| 13 Primary postpartum haemorrhage (> 500 mL) | 1 | 294 | Risk Ratio (M-H, Fixed, 95% CI) | 1.66 [0.88, 3.12] |
| 14 Need for postpartum blood transfusion | 1 | 294 | Risk Ratio (M-H, Fixed, 95% CI) | 7.39 [0.92, 59.33] |
| 15 Postnatal depression | 1 | 294 | Risk Ratio (M-H, Fixed, 95% CI) | 0.82 [0.51, 1.32] |
| 16 Adverse effect women readmitted to hospital | 1 | 266 | Risk Ratio (M-H, Fixed, 95% CI) | 1.14 [0.43, 3.06] |
| 17 Adverse effect infant readmitted to hospital | 1 | 266 | Risk Ratio (M-H, Fixed, 95% CI) | 0.9 [0.38, 2.14] |
| 18 Maternal admission to HDU/ICU | 1 | 294 | Risk Ratio (M-H, Fixed, 95% CI) | 3.70 [0.78, 17.50] |

**Comparison 3. Nulliparous versus multiparous**

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Use of pharmacological pain relief/anaesthesia | 3 | 430 | Risk Ratio (M-H, Random, 95% CI) | 0.94 [0.70, 1.27] |
| 1.1 Nulliparous women | 3 | 363 | Risk Ratio (M-H, Random, 95% CI) | 0.85 [0.57, 1.28] |
| 1.2 Multiparous women | 1 | 67 | Risk Ratio (M-H, Random, 95% CI) | 1.12 [0.78, 1.62] |
| 2 Spontaneous vaginal birth | 3 | 420 | Risk Ratio (M-H, Random, 95% CI) | 1.01 [0.81, 1.25] |
| 2.1 Nulliparous women | 3 | 353 | Risk Ratio (M-H, Random, 95% CI) | 1.02 [0.75, 1.39] |
| 2.2 Multiparous women | 1 | 67 | Risk Ratio (M-H, Random, 95% CI) | 1.01 [0.77, 1.33] |

### Comparison 4. < 4 sessions versus 4 or more sessions

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Use of pharmacological pain relief/anaesthesia | 5 | 992 | Risk Ratio (M-H, Random, 95% CI) | 0.62 [0.35, 1.09] |
| 1.1 < 4 sessions | 1 | 305 | Risk Ratio (M-H, Random, 95% CI) | 1.07 [0.95, 1.20] |
| 1.2 4 or more sessions | 4 | 687 | Risk Ratio (M-H, Random, 95% CI) | 0.52 [0.27, 1.01] |
| 2 Spontaneous vaginal birth | 4 | 472 | Risk Ratio (M-H, Random, 95% CI) | 1.35 [0.93, 1.96] |
| 2.1 < 4 sessions | 1 | 305 | Risk Ratio (M-H, Random, 95% CI) | 0.91 [0.75, 1.10] |
| 2.2 4 or more sessions | 3 | 167 | Risk Ratio (M-H, Random, 95% CI) | 1.59 [1.06, 2.38] |

### Comparison 5. Individual sessions versus group sessions

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Use of pharmacological pain relief/anaesthesia | 6 | 1032 | Risk Ratio (M-H, Random, 95% CI) | 0.63 [0.39, 1.01] |
| 1.1 Group sessions | 2 | 365 | Risk Ratio (M-H, Random, 95% CI) | 0.50 [0.09, 2.92] |
| 1.2 Individual sessions | 4 | 667 | Risk Ratio (M-H, Random, 95% CI) | 0.65 [0.39, 1.08] |
| 2 Spontaneous vaginal birth | 4 | 472 | Risk Ratio (M-H, Random, 95% CI) | 1.35 [0.93, 1.96] |
| 2.1 Group sessions | 2 | 365 | Risk Ratio (M-H, Random, 95% CI) | 1.17 [0.67, 2.04] |
| 2.2 Individual sessions | 2 | 107 | Risk Ratio (M-H, Random, 95% CI) | 1.64 [0.79, 3.42] |

### Comparison 6. Hypnosis plus audio CD/tape versus hypnosis no audio CD/tape versus nurse/audio CD only

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Use of pharmacological pain relief/anaesthesia | 4 | 615 | Risk Ratio (M-H, Random, 95% CI) | 1.04 [0.79, 1.37] |
| 1.1 Hypnosis plus audio CD/tape | 2 | 289 | Risk Ratio (M-H, Random, 95% CI) | 0.50 [0.08, 3.06] |
| 1.2 Hypnosis, no audio CD/tape | 2 | 107 | Risk Ratio (M-H, Random, 95% CI) | 1.50 [0.57, 3.93] |
| 1.3 Nurse/audio CD only | 1 | 219 | Risk Ratio (M-H, Random, 95% CI) | 1.01 [0.86, 1.18] |
| 2 Spontaneous vaginal birth | 4 | 615 | Risk Ratio (M-H, Random, 95% CI) | 1.24 [0.94, 1.63] |
| 2.1 Hypnosis plus audio CD/tape | 2 | 289 | Risk Ratio (M-H, Random, 95% CI) | 1.17 [0.67, 2.05] |
| 2.2 Hypnosis, no audio CD/tape | 2 | 107 | Risk Ratio (M-H, Random, 95% CI) | 1.64 [0.79, 3.42] |
| 2.3 Nurse/audio CD only | 1 | 219 | Risk Ratio (M-H, Random, 95% CI) | 0.97 [0.77, 1.22] |

**Comparison 7. Hypnosis preparation for labour versus hypnosis during labour**

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Use of pharmacological pain relief/anaesthesia | 6 | 1032 | Risk Ratio (M-H, Random, 95% CI) | 0.63 [0.39, 1.01] |
| 1.1 Hypnosis preparation for labour | 5 | 992 | Risk Ratio (M-H, Random, 95% CI) | 0.62 [0.35, 1.09] |
| 1.2 Hypnosis during labour | 1 | 40 | Risk Ratio (M-H, Random, 95% CI) | 0.67 [0.48, 0.94] |

**Comparison 8. High hypnotisability versus low hypnotisability**

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Use of pharmacological pain relief/anaesthesia | 2 | 326 | Risk Ratio (M-H, Random, 95% CI) | 0.86 [0.57, 1.30] |
| 1.1 High hypnotisability | 2 | 173 | Risk Ratio (M-H, Random, 95% CI) | 0.43 [0.04, 4.56] |
| 1.2 Low hypnotisability | 2 | 153 | Risk Ratio (M-H, Random, 95% CI) | 0.61 [0.13, 2.91] |
| 2 Spontaneous vaginal birth | 2 | 326 | Risk Ratio (M-H, Random, 95% CI) | 1.09 [0.81, 1.46] |
| 2.1 High hypnotisability | 2 | 173 | Risk Ratio (M-H, Random, 95% CI) | 1.10 [0.69, 1.75] |
| 2.2 Low hypnotisability | 2 | 153 | Risk Ratio (M-H, Random, 95% CI) | 1.19 [0.59, 2.40] |

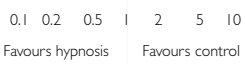
## Analysis 1.1. Comparison 1 Self-hypnosis or hypnotherapy versus control, Outcome 1 Use of pharmacological pain relief/anaesthesia.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 1 Self-hypnosis or hypnotherapy versus control

Outcome: 1 Use of pharmacological pain relief/anaesthesia

| Study or subgroup | Hypnosis n/N | Control n/N | Risk Ratio M-H,Random,95% CI | Weight | Risk Ratio M-H,Random,95% CI |
|---|---|---|---|---|---|
| 1 1st and 2nd trimester | | | | | |
| Mehl-Madrona 2004 | 70/260 | 168/260 | | 18.6 % | 0.42 [ 0.33, 0.52 ] |
| **Subtotal (95% CI)** | **260** | **260** | | **18.6 %** | **0.42 [ 0.33, 0.52 ]** |
| Total events: 70 (Hypnosis), 168 (Control) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 7.82 (P < 0.00001) | | | | | |
| 2 2nd trimester | | | | | |
| Martin 2001 | 10/22 | 14/20 | | 15.5 % | 0.65 [ 0.38, 1.11 ] |
| **Subtotal (95% CI)** | **22** | **20** | | **15.5 %** | **0.65 [ 0.38, 1.11 ]** |
| Total events: 10 (Hypnosis), 14 (Control) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 1.57 (P = 0.12) | | | | | |
| 3 3rd trimester | | | | | |
| Cyna 2011 | 125/154 | 115/151 | | 19.1 % | 1.07 [ 0.95, 1.20 ] |
| Freeman 1986 | 23/29 | 29/36 | | 18.4 % | 0.98 [ 0.77, 1.26 ] |
| Harmon 1990 | 4/30 | 19/30 | | 10.9 % | 0.21 [ 0.08, 0.55 ] |
| Rock 1969 | 14/22 | 17/18 | | 17.6 % | 0.67 [ 0.48, 0.94 ] |
| **Subtotal (95% CI)** | **235** | **235** | | **66.0 %** | **0.78 [ 0.55, 1.12 ]** |
| Total events: 166 (Hypnosis), 180 (Control) | | | | | |
| Heterogeneity: $Tau^2$ = 0.10; $Chi^2$ = 18.70, df = 3 (P = 0.00032); $I^2$ =84% | | | | | |
| Test for overall effect: Z = 1.34 (P = 0.18) | | | | | |
| **Total (95% CI)** | **517** | **515** | | **100.0 %** | **0.63 [ 0.39, 1.01 ]** |
| Total events: 246 (Hypnosis), 362 (Control) | | | | | |
| Heterogeneity: $Tau^2$ = 0.30; $Chi^2$ = 91.01, df = 5 (P<0.00001); $I^2$ =95% | | | | | |
| Test for overall effect: Z = 1.90 (P = 0.058) | | | | | |
| Test for subgroup differences: $Chi^2$ = 9.51, df = 2 (P = 0.01), $I^2$ =79% | | | | | |



## Analysis 1.2. Comparison 1 Self-hypnosis or hypnotherapy versus control, Outcome 2 Satisfaction with pain relief.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 1 Self-hypnosis or hypnotherapy versus control

Outcome: 2 Satisfaction with pain relief

| Study or subgroup | Hypnosis n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Cyna 2011 | 112/136 | 99/128 | | 100.0 % | 1.06 [ 0.94, 1.20 ] |
| **Total (95% CI)** | **136** | **128** | | **100.0 %** | **1.06 [ 0.94, 1.20 ]** |
| Total events: 112 (Hypnosis), 99 (Control) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 1.01 (P = 0.31) | | | | | |
| Test for subgroup differences: Not applicable | | | | | |

### Analysis 1.3. Comparison 1 Self-hypnosis or hypnotherapy versus control, Outcome 3 Spontaneous vaginal birth.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 1 Self-hypnosis or hypnotherapy versus control

Outcome: 3 Spontaneous vaginal birth

| Study or subgroup | Hypnosis n/N | Control n/N | Risk Ratio M-H,Random,95% CI | Weight | Risk Ratio M-H,Random,95% CI |
|---|---|---|---|---|---|
| 1 2nd trimester | | | | | |
| Martin 2001 | 22/22 | 8/20 | | 19.6 % | 2.42 [ 1.43, 4.07 ] |
| **Subtotal (95% CI)** | **22** | **20** | | **19.6 %** | **2.42 [ 1.43, 4.07 ]** |
| Total events: 22 (Hypnosis), 8 (Control) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 3.31 (P = 0.00093) | | | | | |
| 2 3rd trimester | | | | | |
| Cyna 2011 | 85/154 | 92/151 | | 29.6 % | 0.91 [ 0.75, 1.10 ] |
| Freeman 1986 | 24/29 | 25/36 | | 27.4 % | 1.19 [ 0.91, 1.57 ] |
| Harmon 1990 | 24/30 | 15/30 | | 23.4 % | 1.60 [ 1.07, 2.39 ] |
| **Subtotal (95% CI)** | **213** | **217** | | **80.4 %** | **1.16 [ 0.85, 1.57 ]** |
| Total events: 133 (Hypnosis), 132 (Control) | | | | | |
| Heterogeneity: $Tau^2$ = 0.05; $Chi^2$ = 7.44, df = 2 (P = 0.02); $I^2$ =73% | | | | | |
| Test for overall effect: Z = 0.91 (P = 0.36) | | | | | |
| **Total (95% CI)** | **235** | **237** | | **100.0 %** | **1.35 [ 0.93, 1.96 ]** |
| Total events: 155 (Hypnosis), 140 (Control) | | | | | |
| Heterogeneity: $Tau^2$ = 0.11; $Chi^2$ = 16.31, df = 3 (P = 0.00098); $I^2$ =82% | | | | | |
| Test for overall effect: Z = 1.60 (P = 0.11) | | | | | |
| Test for subgroup differences: $Chi^2$ = 5.68, df = 1 (P = 0.02), $I^2$ =82% | | | | | |

### Analysis 1.4. Comparison 1 Self-hypnosis or hypnotherapy versus control, Outcome 4 Pain intensity (scale 0 no pain; 5 excruciating).

Review: Hypnosis for pain management during labour and childbirth

Comparison: 1 Self-hypnosis or hypnotherapy versus control

Outcome: 4 Pain intensity (scale 0 no pain; 5 excruciating)

| Study or subgroup | Hypnosis N | Mean(SD) | Control N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Weight | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|---|
| Harmon 1990 | 30 | 2.9 (0.7) | 30 | 3.6 (0.6) | | 100.0 % | -0.70 [ -1.03, -0.37 ] |
| **Total (95% CI)** | **30** | | **30** | | | **100.0 %** | **-0.70 [ -1.03, -0.37 ]** |

Heterogeneity: not applicable

Test for overall effect: Z = 4.16 (P = 0.000032)

Test for subgroup differences: Not applicable


### Analysis 1.5. Comparison 1 Self-hypnosis or hypnotherapy versus control, Outcome 5 Satisfaction with childbirth experience.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 1 Self-hypnosis or hypnotherapy versus control

Outcome: 5 Satisfaction with childbirth experience

| Study or subgroup | Hypnosis n/N | Control n/N | Risk Ratio M-H,Random,95% CI | Weight | Risk Ratio M-H,Random,95% CI |
|---|---|---|---|---|---|
| Cyna 2011 | 108/154 | 118/151 | | 56.3 % | 0.90 [ 0.79, 1.03 ] |
| Freeman 1986 | 15/29 | 8/36 | | 43.7 % | 2.33 [ 1.15, 4.71 ] |
| **Total (95% CI)** | **183** | **187** | | **100.0 %** | **1.36 [ 0.52, 3.59 ]** |

Total events: 123 (Hypnosis), 126 (Control)

Heterogeneity: $Tau^2 = 0.43$; $Chi^2 = 7.42$, df = 1 (P = 0.01); $I^2 = 87\%$

Test for overall effect: Z = 0.62 (P = 0.53)

Test for subgroup differences: Not applicable

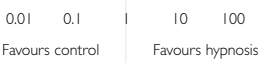
### Analysis 1.6. Comparison 1 Self-hypnosis or hypnotherapy versus control, Outcome 6 Breastfeeding at discharge (any).

Review: Hypnosis for pain management during labour and childbirth

Comparison: 1 Self-hypnosis or hypnotherapy versus control

Outcome: 6 Breastfeeding at discharge (any)

| Study or subgroup | Hypnosis n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Cyna 2011 | 150/153 | 148/151 | | 100.0 % | 1.00 [ 0.97, 1.03 ] |
| **Total (95% CI)** | **153** | **151** | | **100.0 %** | **1.00 [ 0.97, 1.03 ]** |
| Total events: 150 (Hypnosis), 148 (Control) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 0.02 (P = 0.99) | | | | | |
| Test for subgroup differences: Not applicable | | | | | |



### Analysis 1.7. Comparison 1 Self-hypnosis or hypnotherapy versus control, Outcome 7 Assisted vaginal birth.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 1 Self-hypnosis or hypnotherapy versus control

Outcome: 7 Assisted vaginal birth

| Study or subgroup | Hypnosis n/N | Control n/N | Risk Ratio M-H,Random,95% CI | Weight | Risk Ratio M-H,Random,95% CI |
|---|---|---|---|---|---|
| Cyna 2011 | 31/154 | 30/151 | | 41.9 % | 1.01 [ 0.65, 1.59 ] |
| Freeman 1986 | 5/29 | 11/36 | | 24.7 % | 0.56 [ 0.22, 1.44 ] |
| Harmon 1990 | 6/30 | 15/30 | | 28.9 % | 0.40 [ 0.18, 0.89 ] |
| Martin 2001 | 0/22 | 4/22 | | 4.5 % | 0.11 [ 0.01, 1.95 ] |
| **Total (95% CI)** | **235** | **239** | | **100.0 %** | **0.61 [ 0.32, 1.15 ]** |

Total events: 42 (Hypnosis), 60 (Control)

Heterogeneity: $Tau^2 = 0.20$; $Chi^2 = 6.20$, df = 3 (P = 0.10); $I^2 = 52\%$

Test for overall effect: Z = 1.54 (P = 0.12)

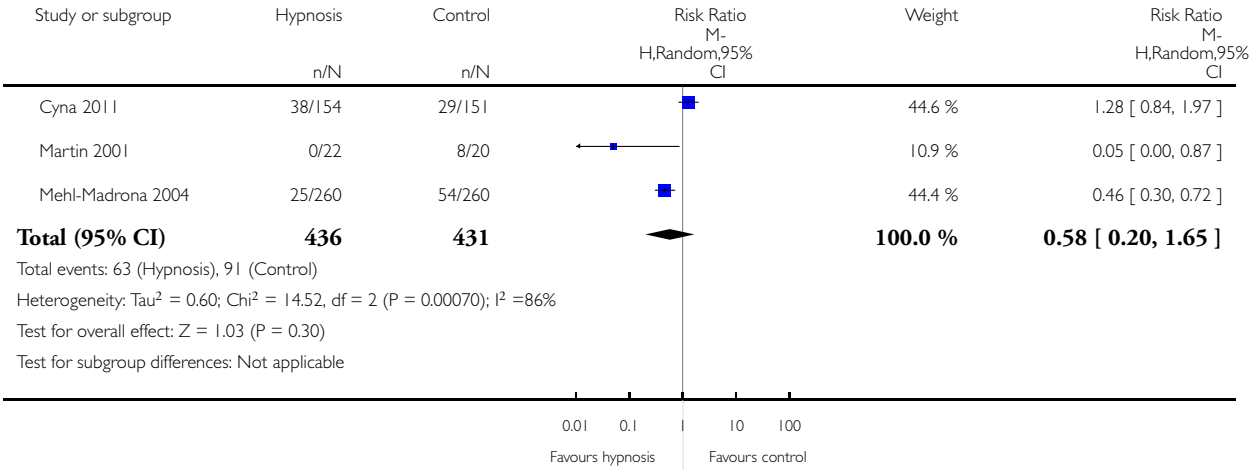
Test for subgroup differences: Not applicable

### Analysis 1.8. Comparison 1 Self-hypnosis or hypnotherapy versus control, Outcome 8 Caesarean section.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 1 Self-hypnosis or hypnotherapy versus control

Outcome: 8 Caesarean section



### Analysis 1.9. Comparison 1 Self-hypnosis or hypnotherapy versus control, Outcome 9 Admission to neonatal intensive care unit.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 1 Self-hypnosis or hypnotherapy versus control

Outcome: 9 Admission to neonatal intensive care unit

| Study or subgroup | Hypnosis n/N | Control n/N | Risk Ratio M-H,Random,95% CI | Weight | Risk Ratio M-H,Random,95% CI |
|---|---|---|---|---|---|
| Cyna 2011 | 53/154 | 51/151 | | 67.7 % | 1.02 [ 0.75, 1.39 ] |
| Martin 2001 | 1/22 | 5/20 | | 32.3 % | 0.18 [ 0.02, 1.43 ] |
| **Total (95% CI)** | **176** | **171** | | **100.0 %** | **0.58 [ 0.12, 2.89 ]** |

Total events: 54 (Hypnosis), 56 (Control)

Heterogeneity: $Tau^2 = 0.96$; $Chi^2 = 2.69$, df = 1 (P = 0.10); $I^2 = 63\%$

Test for overall effect: Z = 0.66 (P = 0.51)

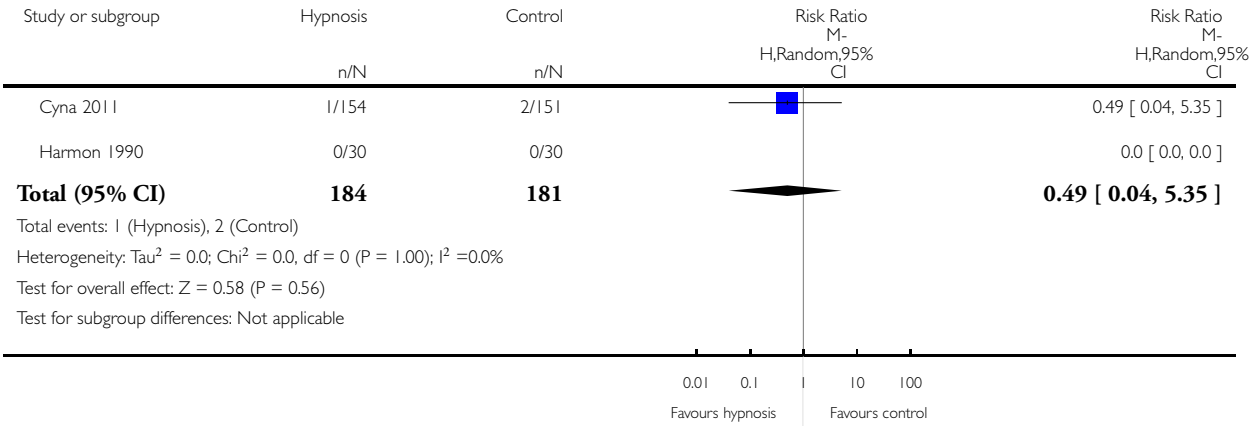
Test for subgroup differences: Not applicable

## Analysis 1.10. Comparison 1 Self-hypnosis or hypnotherapy versus control, Outcome 10 Apgar score less than 7 at 5 minutes.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 1 Self-hypnosis or hypnotherapy versus control

Outcome: 10 Apgar score less than 7 at 5 minutes



### Analysis 1.11. Comparison 1 Self-hypnosis or hypnotherapy versus control, Outcome 11 Use of epidural/neuroaxial block.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 1 Self-hypnosis or hypnotherapy versus control

Outcome: 11 Use of epidural/neuroaxial block

| Study or subgroup | Hypnosis n/N | Control n/N | Risk Ratio M-H,Random,95% CI | Weight | Risk Ratio M-H,Random,95% CI |
|---|---|---|---|---|---|
| Cyna 2011 | 78/154 | 71/151 | | 32.9 % | 1.08 [ 0.86, 1.36 ] |
| Freeman 1986 | 8/29 | 9/36 | | 27.1 % | 1.10 [ 0.49, 2.50 ] |
| Mehl-Madrona 2004 | 42/260 | 141/260 | | 32.5 % | 0.30 [ 0.22, 0.40 ] |
| Rock 1969 | 1/22 | 0/18 | | 7.5 % | 2.48 [ 0.11, 57.40 ] |
| **Total (95% CI)** | **465** | **465** | | **100.0 %** | **0.76 [ 0.29, 2.02 ]** |

Total events: 129 (Hypnosis), 221 (Control)

Heterogeneity: $Tau^2 = 0.74$; $Chi^2 = 49.78$, df = 3 (P<0.00001); $I^2$ =94%

Test for overall effect: Z = 0.55 (P = 0.58)

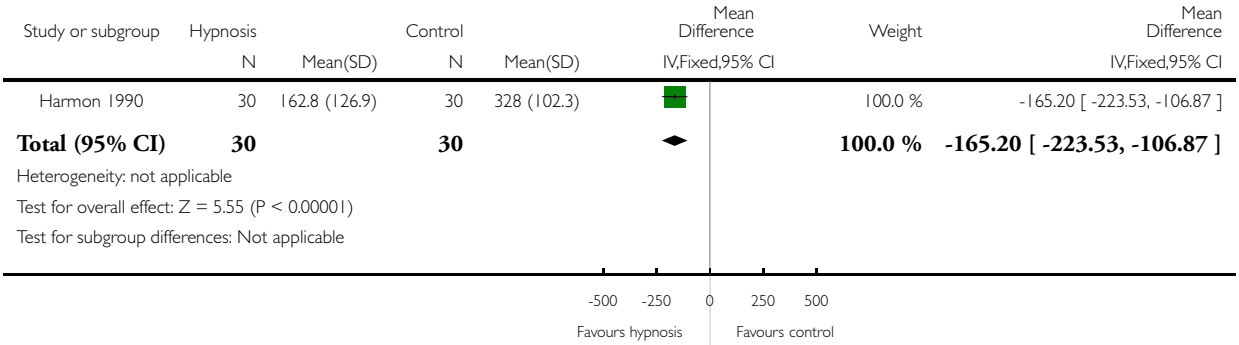
Test for subgroup differences: Not applicable

### Analysis 1.12. Comparison 1 Self-hypnosis or hypnotherapy versus control, Outcome 12 Length of labour from 5 cm dilation to birth (minutes).

Review: Hypnosis for pain management during labour and childbirth

Comparison: 1 Self-hypnosis or hypnotherapy versus control

Outcome: 12 Length of labour from 5 cm dilation to birth (minutes)

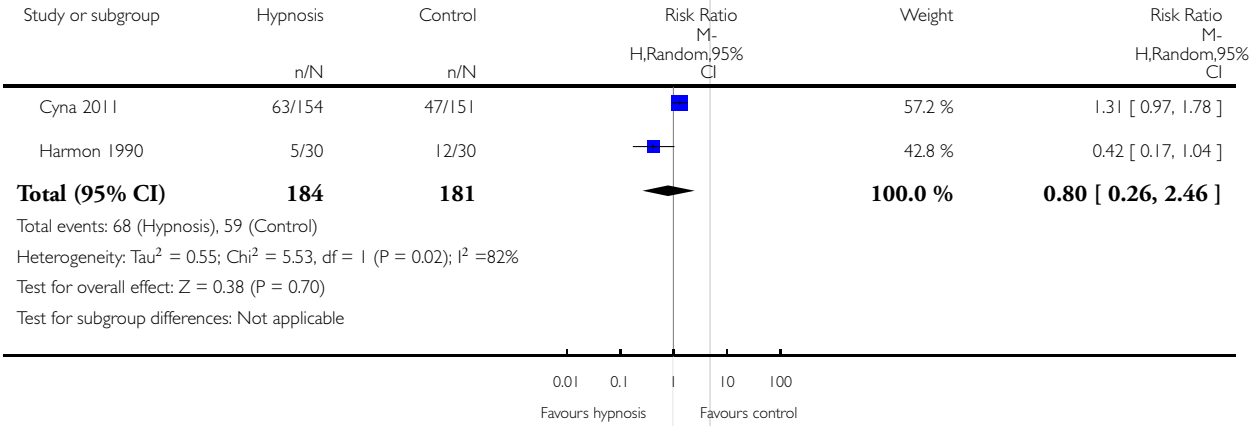



### Analysis 1.13. Comparison 1 Self-hypnosis or hypnotherapy versus control, Outcome 13 Induction of labour.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 1 Self-hypnosis or hypnotherapy versus control

Outcome: 13 Induction of labour

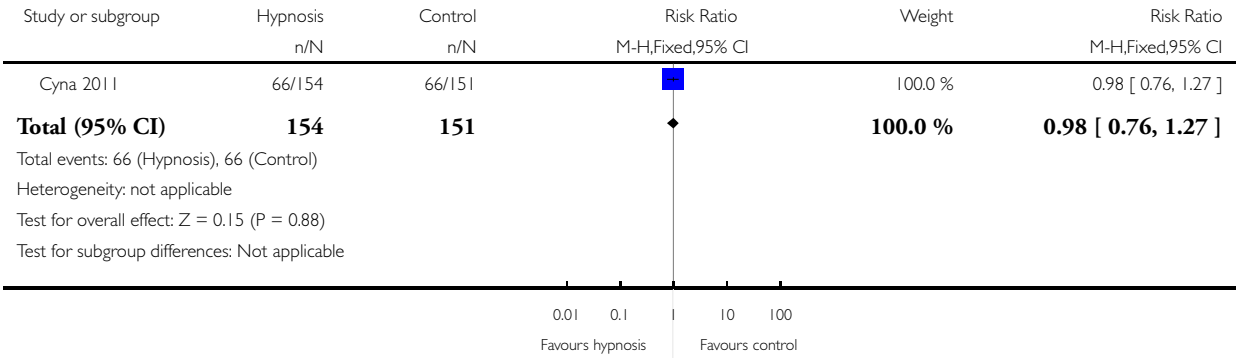


### Analysis 1.14. Comparison 1 Self-hypnosis or hypnotherapy versus control, Outcome 14 Augmentation of labour.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 1 Self-hypnosis or hypnotherapy versus control

Outcome: 14 Augmentation of labour

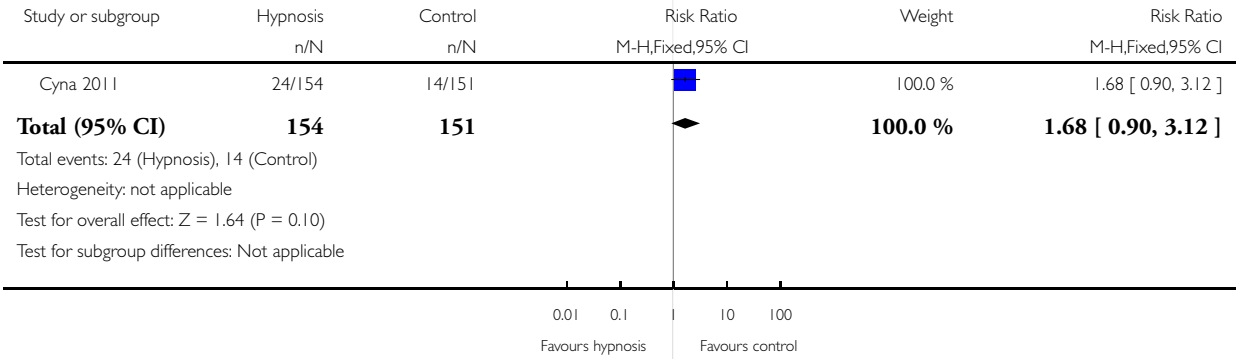



### Analysis 1.15. Comparison 1 Self-hypnosis or hypnotherapy versus control, Outcome 15 Primary postpartum haemorrhage (> 500 mL).

Review: Hypnosis for pain management during labour and childbirth

Comparison: 1 Self-hypnosis or hypnotherapy versus control

Outcome: 15 Primary postpartum haemorrhage (> 500 mL)



### Analysis 1.16. Comparison 1 Self-hypnosis or hypnotherapy versus control, Outcome 16 Need for postpartum blood transfusion.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 1 Self-hypnosis or hypnotherapy versus control

Outcome: 16 Need for postpartum blood transfusion

| Study or subgroup | Hypnosis n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Cyna 2011 | 4/154 | 1/151 | | 100.0 % | 3.92 [ 0.44, 34.69 ] |
| **Total (95% CI)** | **154** | **151** | | **100.0 %** | **3.92 [ 0.44, 34.69 ]** |

Total events: 4 (Hypnosis), 1 (Control)
Heterogeneity: not applicable
Test for overall effect: Z = 1.23 (P = 0.22)
Test for subgroup differences: Not applicable


### Analysis 1.17. Comparison 1 Self-hypnosis or hypnotherapy versus control, Outcome 17 Postnatal depression.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 1 Self-hypnosis or hypnotherapy versus control

Outcome: 17 Postnatal depression

| Study or subgroup | Hypnosis n/N | Control n/N | Risk Ratio M-H,Random,95% CI | Risk Ratio M-H,Random,95% CI |
|---|---|---|---|---|
| Cyna 2011 | 37/154 | 31/151 | | 1.17 [ 0.77, 1.78 ] |
| Rock 1969 | 0/22 | 0/18 | | 0.0 [ 0.0, 0.0 ] |
| **Total (95% CI)** | **176** | **169** | | **1.17 [ 0.77, 1.78 ]** |

Total events: 37 (Hypnosis), 31 (Control)
Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 0.0$, df = 0 (P = 1.00); $I^2 = 0.0\%$
Test for overall effect: Z = 0.73 (P = 0.46)
Test for subgroup differences: Not applicable

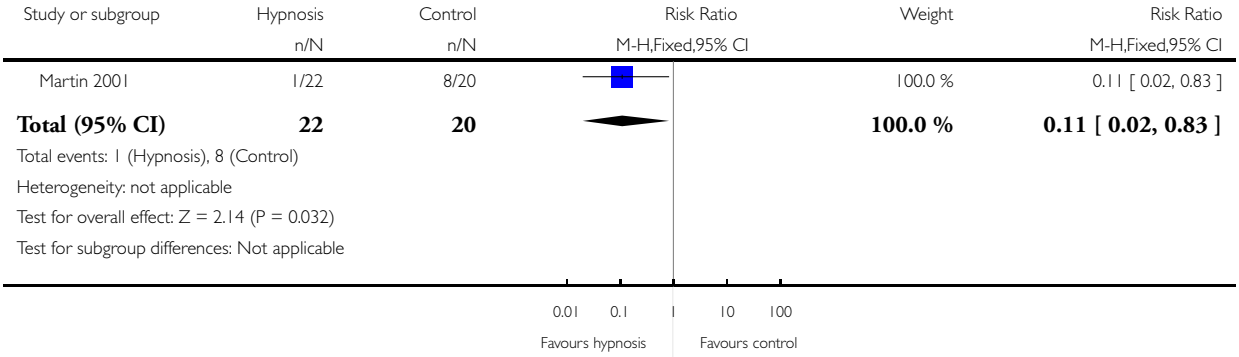
### Analysis 1.18. Comparison 1 Self-hypnosis or hypnotherapy versus control, Outcome 18 Number of maternal days in hospital after birth (> 2 days).

Review: Hypnosis for pain management during labour and childbirth

Comparison: 1 Self-hypnosis or hypnotherapy versus control

Outcome: 18 Number of maternal days in hospital after birth (> 2 days)

| Study or subgroup | Hypnosis n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Martin 2001 | 1/22 | 8/20 | | 100.0 % | 0.11 [ 0.02, 0.83 ] |
| **Total (95% CI)** | **22** | **20** | | **100.0 %** | **0.11 [ 0.02, 0.83 ]** |
| Total events: 1 (Hypnosis), 8 (Control) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 2.14 (P = 0.032) | | | | | |
| Test for subgroup differences: Not applicable | | | | | |



### Analysis 1.19. Comparison 1 Self-hypnosis or hypnotherapy versus control, Outcome 19 Other adverse events - newborn resuscitation.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 1 Self-hypnosis or hypnotherapy versus control

Outcome: 19 Other adverse events - newborn resuscitation

| Study or subgroup | Hypnosis n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Mehl-Madrona 2004 | 2/260 | 3/260 | | 100.0 % | 0.67 [ 0.11, 3.96 ] |
| **Total (95% CI)** | **260** | **260** | | **100.0 %** | **0.67 [ 0.11, 3.96 ]** |

Total events: 2 (Hypnosis), 3 (Control)
Heterogeneity: not applicable
Test for overall effect: Z = 0.45 (P = 0.66)
Test for subgroup differences: Not applicable


### Analysis 1.20. Comparison 1 Self-hypnosis or hypnotherapy versus control, Outcome 20 Other adverse events - women readmitted to hospital.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 1 Self-hypnosis or hypnotherapy versus control

Outcome: 20 Other adverse events - women readmitted to hospital

| Study or subgroup | Hypnosis n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Cyna 2011 | 11/134 | 7/133 | | 100.0 % | 1.56 [ 0.62, 3.90 ] |
| **Total (95% CI)** | **134** | **133** | | **100.0 %** | **1.56 [ 0.62, 3.90 ]** |

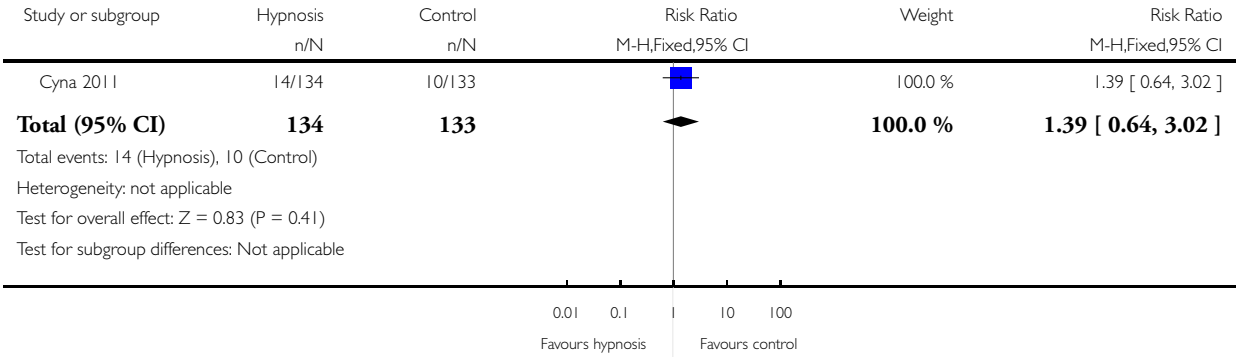
Total events: 11 (Hypnosis), 7 (Control)
Heterogeneity: not applicable
Test for overall effect: Z = 0.95 (P = 0.34)
Test for subgroup differences: Not applicable

### Analysis 1.21. Comparison 1 Self-hypnosis or hypnotherapy versus control, Outcome 21 Other adverse events - infants readmitted to hospital.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 1 Self-hypnosis or hypnotherapy versus control

Outcome: 21 Other adverse events - infants readmitted to hospital

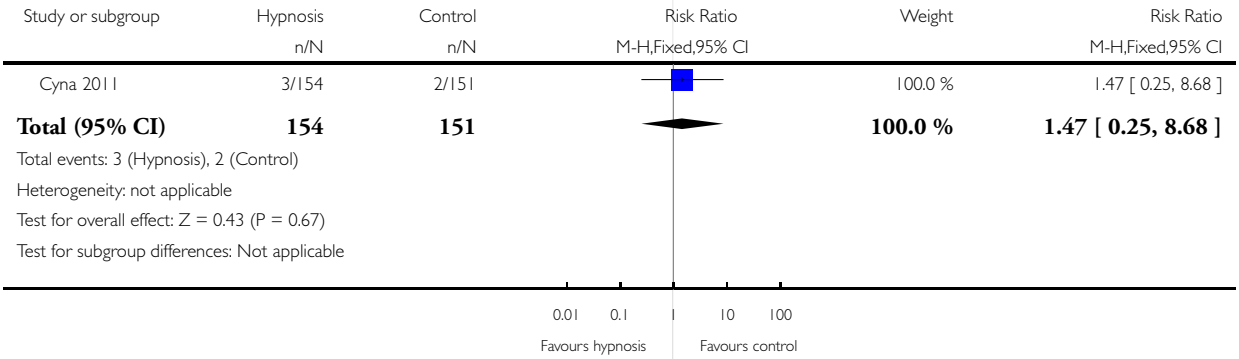



### Analysis 1.22. Comparison 1 Self-hypnosis or hypnotherapy versus control, Outcome 22 Other adverse events - maternal admission to HDU/ICU.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 1 Self-hypnosis or hypnotherapy versus control

Outcome: 22 Other adverse events - maternal admission to HDU/ICU



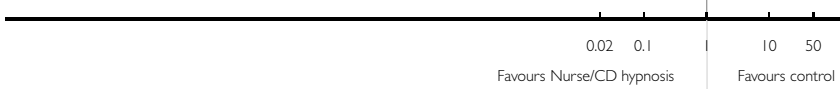
### Analysis 2.1. Comparison 2 Nurse/CD hypnosis versus control, Outcome 1 Use of pharmacological pain relief/anaesthesia.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 2 Nurse/CD hypnosis versus control

Outcome: 1 Use of pharmacological pain relief/anaesthesia

| Study or subgroup | Nurse/CD hypnosis n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Cyna 2011 | 110/143 | 115/151 | | 100.0 % | 1.01 [ 0.89, 1.15 ] |
| **Total (95% CI)** | **143** | **151** | | **100.0 %** | **1.01 [ 0.89, 1.15 ]** |
| Total events: 110 (Nurse/CD hypnosis), 115 (Control) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 0.15 (P = 0.88) | | | | | |
| Test for subgroup differences: Not applicable | | | | | |




### Analysis 2.2. Comparison 2 Nurse/CD hypnosis versus control, Outcome 2 Satisfaction with pain relief.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 2 Nurse/CD hypnosis versus control

Outcome: 2 Satisfaction with pain relief

| Study or subgroup | Nurse/CD hypnosis n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Cyna 2011 | 92/131 | 99/128 | | 100.0 % | 0.91 [ 0.78, 1.05 ] |
| **Total (95% CI)** | **131** | **128** | | **100.0 %** | **0.91 [ 0.78, 1.05 ]** |
| Total events: 92 (Nurse/CD hypnosis), 99 (Control) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 1.30 (P = 0.19) | | | | | |
| Test for subgroup differences: Not applicable | | | | | |

### Analysis 2.3. Comparison 2 Nurse/CD hypnosis versus control, Outcome 3 Spontaneous vaginal birth.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 2 Nurse/CD hypnosis versus control

Outcome: 3 Spontaneous vaginal birth

| Study or subgroup | Nurse/CD hypnosis n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Cyna 2011 | 84/143 | 92/151 | | 100.0 % | 0.96 [ 0.80, 1.16 ] |
| **Total (95% CI)** | **143** | **151** | | **100.0 %** | **0.96 [ 0.80, 1.16 ]** |

Total events: 84 (Nurse/CD hypnosis), 92 (Control)
Heterogeneity: not applicable
Test for overall effect: Z = 0.38 (P = 0.70)
Test for subgroup differences: Not applicable


### Analysis 2.4. Comparison 2 Nurse/CD hypnosis versus control, Outcome 4 Satisfaction with childbirth experience.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 2 Nurse/CD hypnosis versus control

Outcome: 4 Satisfaction with childbirth experience

| Study or subgroup | Nurse/CD hypnosis n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Cyna 2011 | 105/143 | 118/151 | | 100.0 % | 0.94 [ 0.83, 1.07 ] |
| **Total (95% CI)** | **143** | **151** | | **100.0 %** | **0.94 [ 0.83, 1.07 ]** |

Total events: 105 (Nurse/CD hypnosis), 118 (Control)
Heterogeneity: not applicable
Test for overall effect: Z = 0.94 (P = 0.35)
Test for subgroup differences: Not applicable

### Analysis 2.5. Comparison 2 Nurse/CD hypnosis versus control, Outcome 5 Breastfeeding at discharge.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 2 Nurse/CD hypnosis versus control

Outcome: 5 Breastfeeding at discharge

| Study or subgroup | Nurse/CD hypnosis n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Cyna 2011 | 141/143 | 148/151 | | 100.0 % | 1.01 [ 0.98, 1.04 ] |
| **Total (95% CI)** | **143** | **151** | | **100.0 %** | **1.01 [ 0.98, 1.04 ]** |

Total events: 141 (Nurse/CD hypnosis), 148 (Control)
Heterogeneity: not applicable
Test for overall effect: Z = 0.39 (P = 0.70)
Test for subgroup differences: Not applicable


### Analysis 2.6. Comparison 2 Nurse/CD hypnosis versus control, Outcome 6 Assisted vaginal birth.

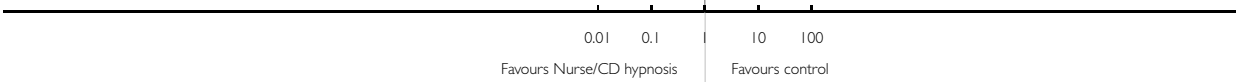
Review: Hypnosis for pain management during labour and childbirth

Comparison: 2 Nurse/CD hypnosis versus control

Outcome: 6 Assisted vaginal birth

| Study or subgroup | Nurse/CD hypnosis n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Cyna 2011 | 34/143 | 30/151 | | 100.0 % | 1.20 [ 0.78, 1.85 ] |
| **Total (95% CI)** | **143** | **151** | | **100.0 %** | **1.20 [ 0.78, 1.85 ]** |

Total events: 34 (Nurse/CD hypnosis), 30 (Control)
Heterogeneity: not applicable
Test for overall effect: Z = 0.81 (P = 0.42)
Test for subgroup differences: Not applicable



### Analysis 2.7. Comparison 2 Nurse/CD hypnosis versus control, Outcome 7 Caesarean section.

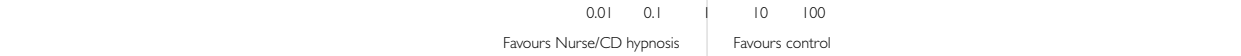
Review: Hypnosis for pain management during labour and childbirth

Comparison: 2 Nurse/CD hypnosis versus control

Outcome: 7 Caesarean section

| Study or subgroup | Nurse/CD hypnosis n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Cyna 2011 | 25/143 | 29/151 | | 100.0 % | 0.91 [ 0.56, 1.48 ] |
| **Total (95% CI)** | **143** | **151** | | **100.0 %** | **0.91 [ 0.56, 1.48 ]** |

Total events: 25 (Nurse/CD hypnosis), 29 (Control)
Heterogeneity: not applicable
Test for overall effect: Z = 0.38 (P = 0.70)
Test for subgroup differences: Not applicable




### Analysis 2.8. Comparison 2 Nurse/CD hypnosis versus control, Outcome 8 Admission to neonatal intensive care unit.

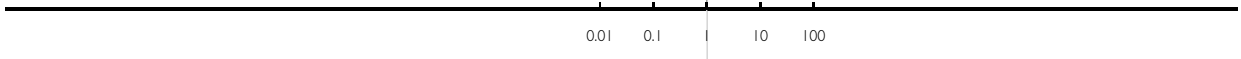
Review: Hypnosis for pain management during labour and childbirth

Comparison: 2 Nurse/CD hypnosis versus control

Outcome: 8 Admission to neonatal intensive care unit

| Study or subgroup | Nurse/CD hypnosis n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Cyna 2011 | 45/143 | 51/151 | | 100.0 % | 0.93 [ 0.67, 1.29 ] |
| **Total (95% CI)** | **143** | **151** | | **100.0 %** | **0.93 [ 0.67, 1.29 ]** |

Total events: 45 (Nurse/CD hypnosis), 51 (Control)
Heterogeneity: not applicable
Test for overall effect: Z = 0.42 (P = 0.67)
Test for subgroup differences: Not applicable

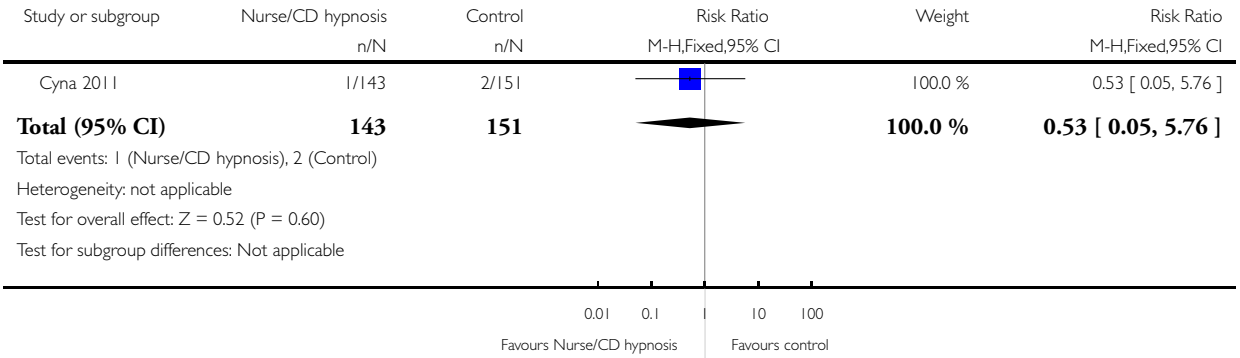


### Analysis 2.9. Comparison 2 Nurse/CD hypnosis versus control, Outcome 9 Apgar score less than 7 at 5 minutes.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 2 Nurse/CD hypnosis versus control

Outcome: 9 Apgar score less than 7 at 5 minutes

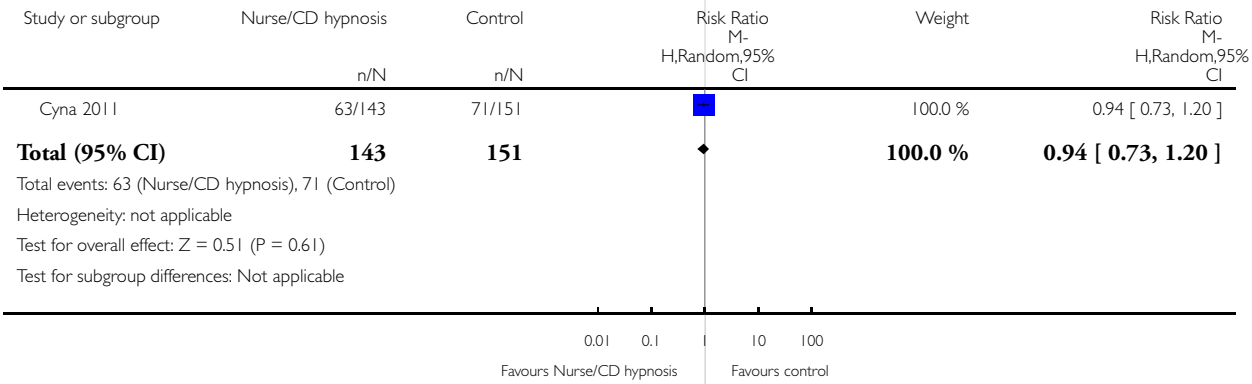



### Analysis 2.10. Comparison 2 Nurse/CD hypnosis versus control, Outcome 10 Use of epidural/neuroaxial block.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 2 Nurse/CD hypnosis versus control

Outcome: 10 Use of epidural/neuroaxial block



### Analysis 2.11. Comparison 2 Nurse/CD hypnosis versus control, Outcome 11 Induction of labour.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 2 Nurse/CD hypnosis versus control

Outcome: 11 Induction of labour

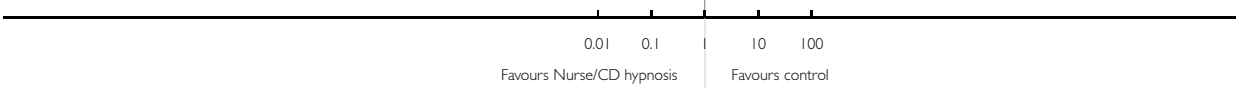
| Study or subgroup | Nurse/CD hypnosis n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Cyna 2011 | 43/143 | 47/151 | | 100.0 % | 0.97 [ 0.68, 1.36 ] |
| **Total (95% CI)** | **143** | **151** | | **100.0 %** | **0.97 [ 0.68, 1.36 ]** |

Total events: 43 (Nurse/CD hypnosis), 47 (Control)

Heterogeneity: not applicable

Test for overall effect: Z = 0.20 (P = 0.84)

Test for subgroup differences: Not applicable




### Analysis 2.12. Comparison 2 Nurse/CD hypnosis versus control, Outcome 12 Augmentation of labour.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 2 Nurse/CD hypnosis versus control

Outcome: 12 Augmentation of labour

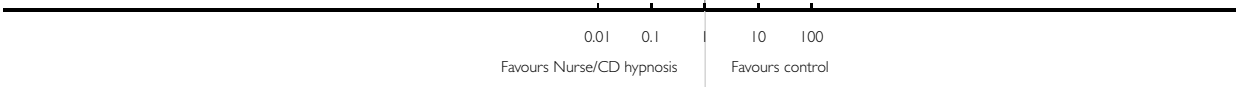
| Study or subgroup | Nurse/CD hypnosis n/N | Control n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Cyna 2011 | 66/143 | 66/151 | | 100.0 % | 1.06 [ 0.82, 1.36 ] |
| **Total (95% CI)** | **143** | **151** | | **100.0 %** | **1.06 [ 0.82, 1.36 ]** |

Total events: 66 (Nurse/CD hypnosis), 66 (Control)

Heterogeneity: not applicable

Test for overall effect: Z = 0.42 (P = 0.67)

Test for subgroup differences: Not applicable

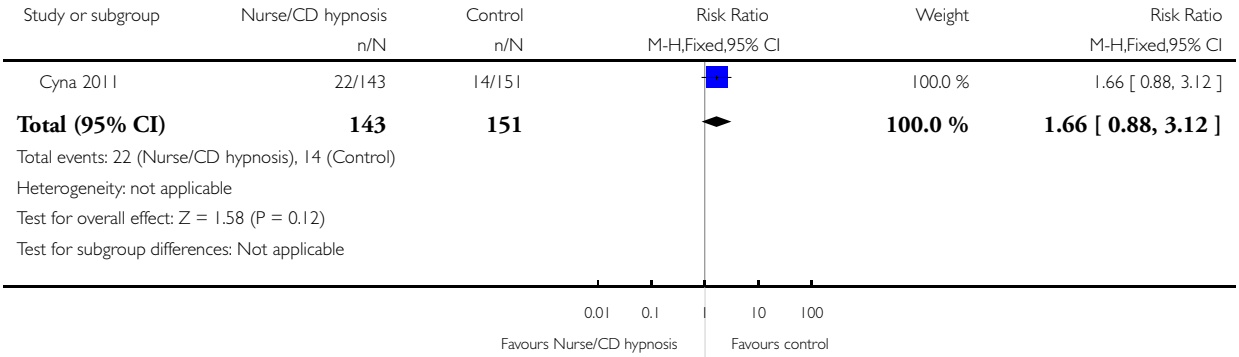


### Analysis 2.13. Comparison 2 Nurse/CD hypnosis versus control, Outcome 13 Primary postpartum haemorrhage (> 500 mL).

Review: Hypnosis for pain management during labour and childbirth

Comparison: 2 Nurse/CD hypnosis versus control

Outcome: 13 Primary postpartum haemorrhage (> 500 mL)

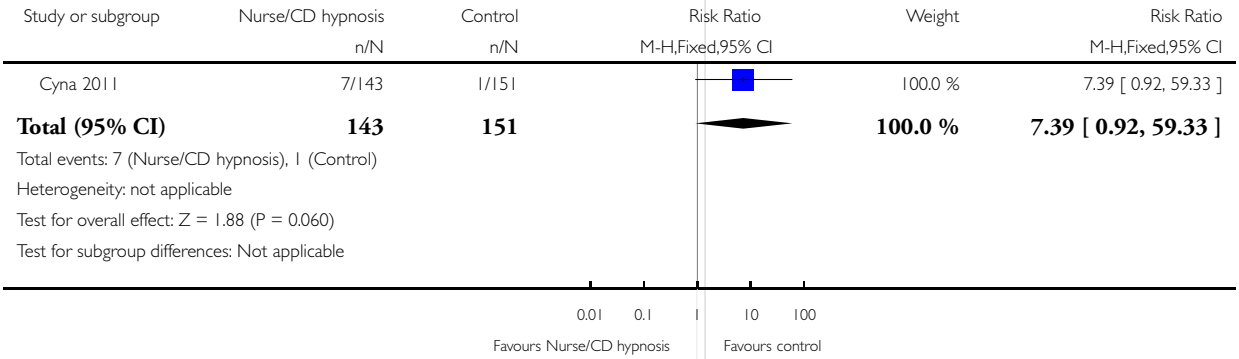



### Analysis 2.14. Comparison 2 Nurse/CD hypnosis versus control, Outcome 14 Need for postpartum blood transfusion.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 2 Nurse/CD hypnosis versus control

Outcome: 14 Need for postpartum blood transfusion

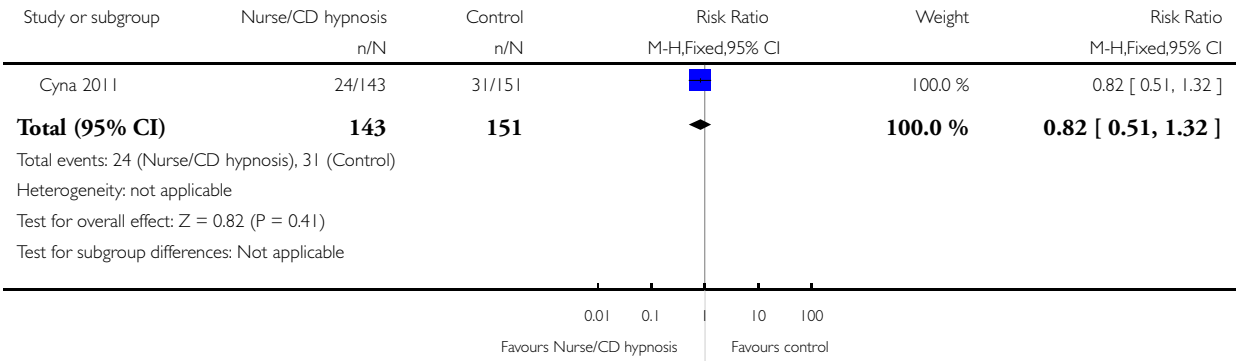


### Analysis 2.15. Comparison 2 Nurse/CD hypnosis versus control, Outcome 15 Postnatal depression.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 2 Nurse/CD hypnosis versus control

Outcome: 15 Postnatal depression

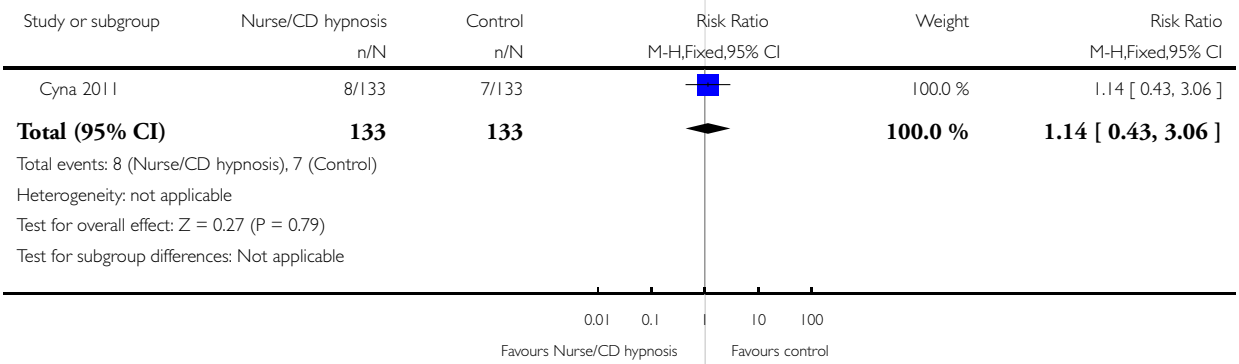



### Analysis 2.16. Comparison 2 Nurse/CD hypnosis versus control, Outcome 16 Adverse effect women readmitted to hospital.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 2 Nurse/CD hypnosis versus control

Outcome: 16 Adverse effect women readmitted to hospital

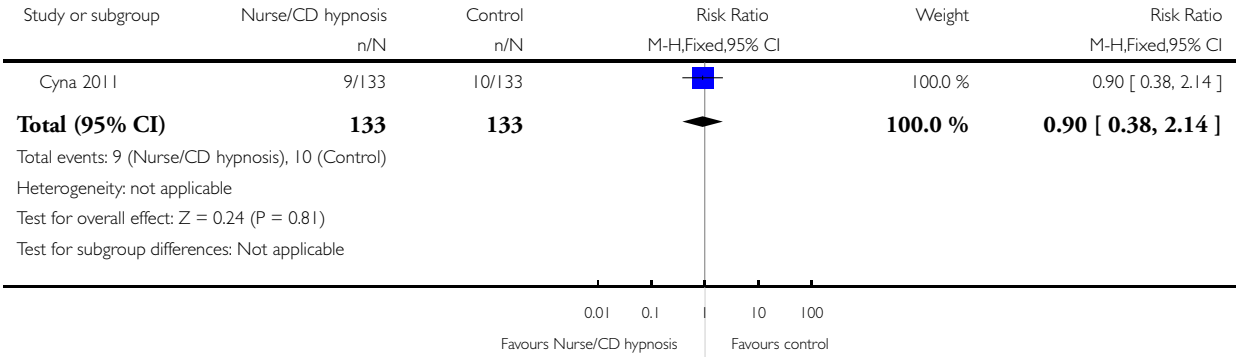


### Analysis 2.17. Comparison 2 Nurse/CD hypnosis versus control, Outcome 17 Adverse effect infant readmitted to hospital.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 2 Nurse/CD hypnosis versus control

Outcome: 17 Adverse effect infant readmitted to hospital

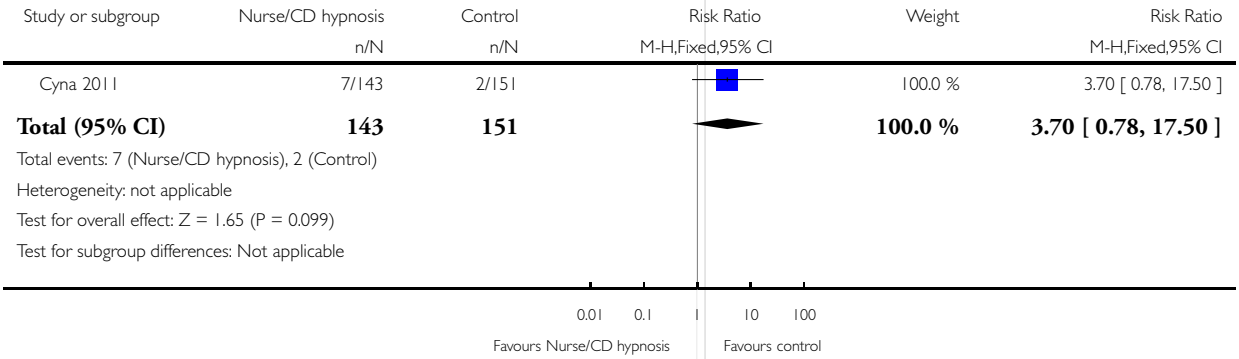



### Analysis 2.18. Comparison 2 Nurse/CD hypnosis versus control, Outcome 18 Maternal admission to HDU/ICU.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 2 Nurse/CD hypnosis versus control

Outcome: 18 Maternal admission to HDU/ICU

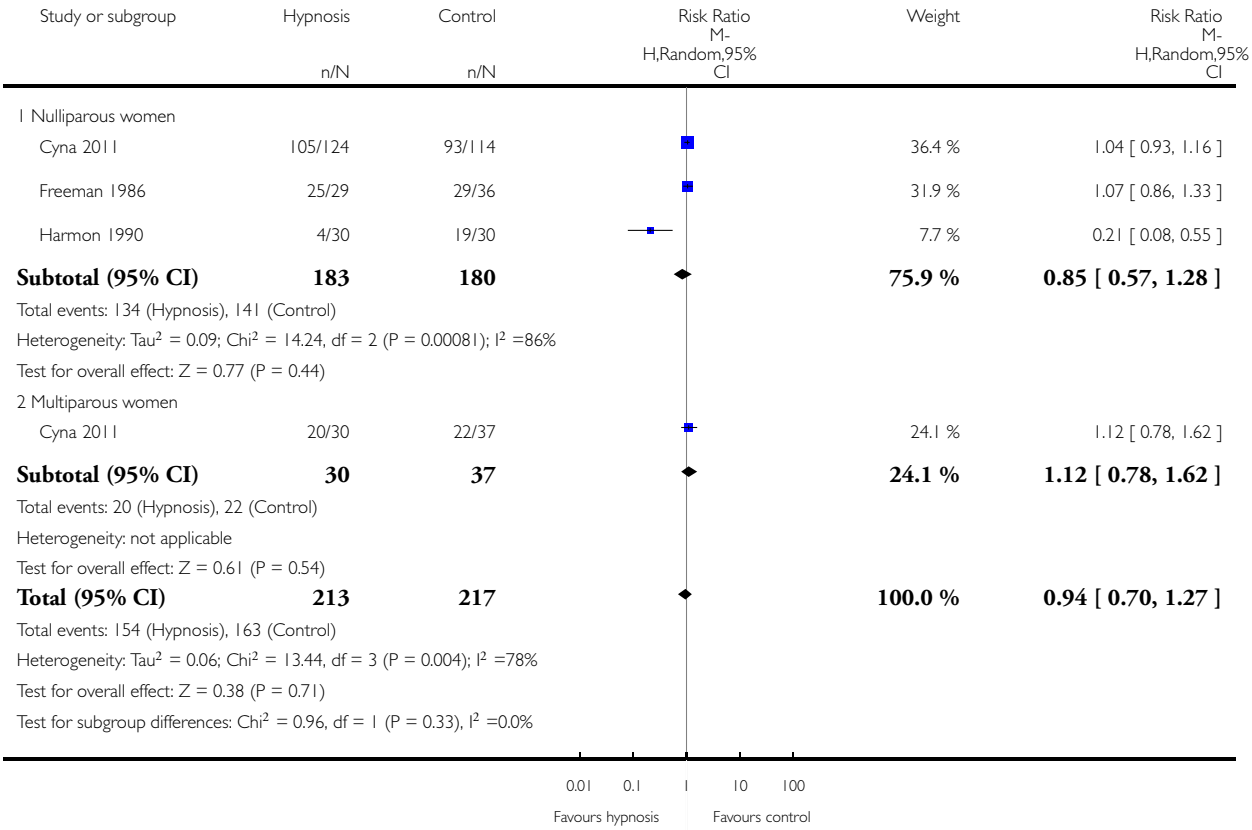


## Analysis 3.1. Comparison 3 Nulliparous versus multiparous, Outcome 1 Use of pharmacological pain relief/anaesthesia.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 3 Nulliparous versus multiparous

Outcome: 1 Use of pharmacological pain relief/anaesthesia



### Analysis 3.2. Comparison 3 Nulliparous versus multiparous, Outcome 2 Spontaneous vaginal birth.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 3 Nulliparous versus multiparous

Outcome: 2 Spontaneous vaginal birth

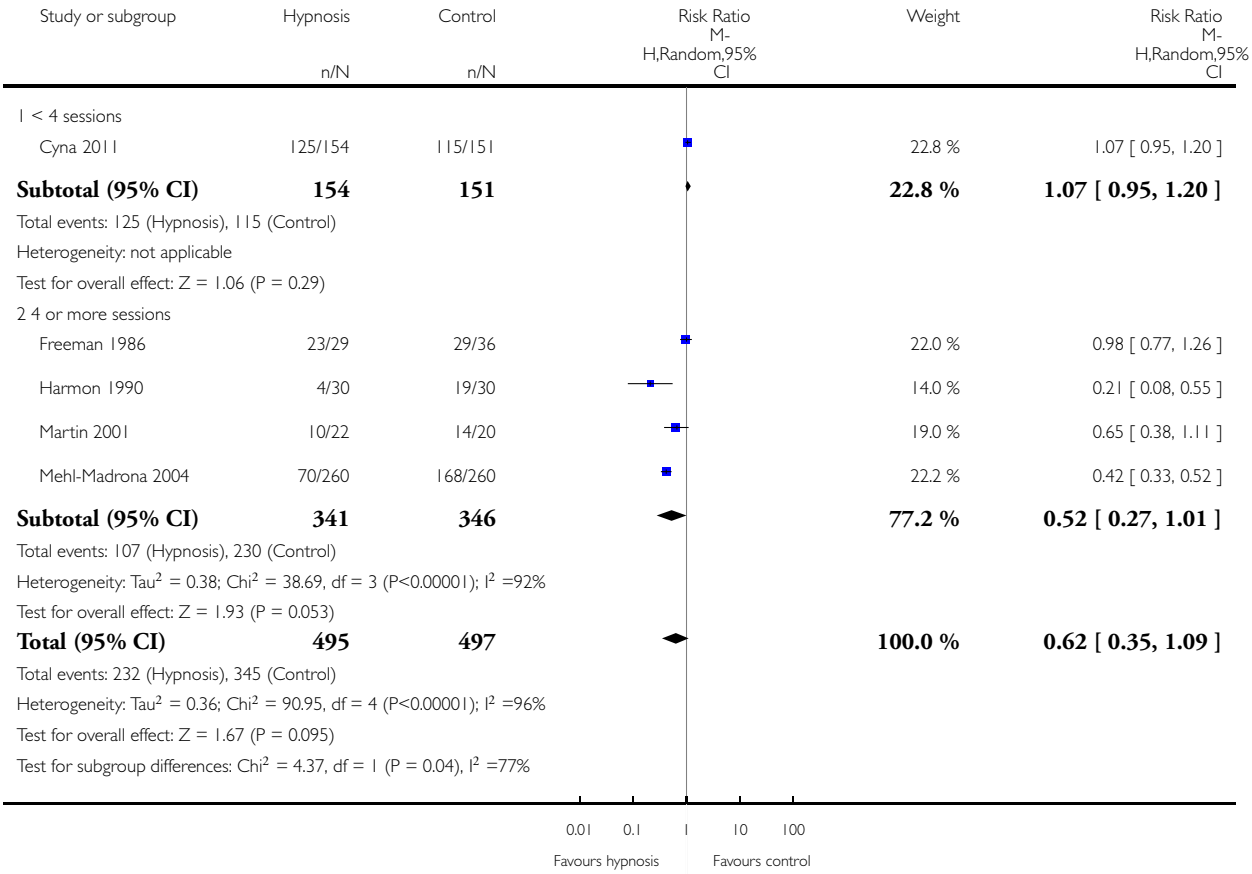
| Study or subgroup | Hypnosis n/N | Control n/N | Risk Ratio M-H,Random,95% CI | Weight | Risk Ratio M-H,Random,95% CI |
|---|---|---|---|---|---|
| 1 Nulliparous women | | | | | |
| Cyna 2011 | 62/124 | 64/114 | | 27.0 % | 0.89 [ 0.70, 1.13 ] |
| Freeman 1986 | 24/29 | 25/26 | | 31.2 % | 0.86 [ 0.72, 1.03 ] |
| Harmon 1990 | 24/30 | 15/30 | | 17.0 % | 1.60 [ 1.07, 2.39 ] |
| **Subtotal (95% CI)** | **183** | **170** | | **75.2 %** | **1.02 [ 0.75, 1.39 ]** |
| Total events: 110 (Hypnosis), 104 (Control) | | | | | |
| Heterogeneity: $Tau^2 = 0.05$; $Chi^2 = 8.35$, df = 2 (P = 0.02); $I^2 = 76\%$ | | | | | |
| Test for overall effect: Z = 0.13 (P = 0.90) | | | | | |
| 2 Multiparous women | | | | | |
| Cyna 2011 | 23/30 | 28/37 | | 24.8 % | 1.01 [ 0.77, 1.33 ] |
| **Subtotal (95% CI)** | **30** | **37** | | **24.8 %** | **1.01 [ 0.77, 1.33 ]** |
| Total events: 23 (Hypnosis), 28 (Control) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 0.09 (P = 0.92) | | | | | |
| **Total (95% CI)** | **213** | **207** | | **100.0 %** | **1.01 [ 0.81, 1.25 ]** |
| Total events: 133 (Hypnosis), 132 (Control) | | | | | |
| Heterogeneity: $Tau^2 = 0.03$; $Chi^2 = 8.51$, df = 3 (P = 0.04); $I^2 = 65\%$ | | | | | |
| Test for overall effect: Z = 0.05 (P = 0.96) | | | | | |
| Test for subgroup differences: $Chi^2 = 0.00$, df = 1 (P = 0.97), $I^2 = 0.0\%$ | | | | | |

## Analysis 4.1. Comparison 4 < 4 sessions versus 4 or more sessions, Outcome 1 Use of pharmacological pain relief/anaesthesia.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 4 < 4 sessions versus 4 or more sessions

Outcome: 1 Use of pharmacological pain relief/anaesthesia



### Analysis 4.2. Comparison 4 < 4 sessions versus 4 or more sessions, Outcome 2 Spontaneous vaginal birth.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 4 < 4 sessions versus 4 or more sessions

Outcome: 2 Spontaneous vaginal birth

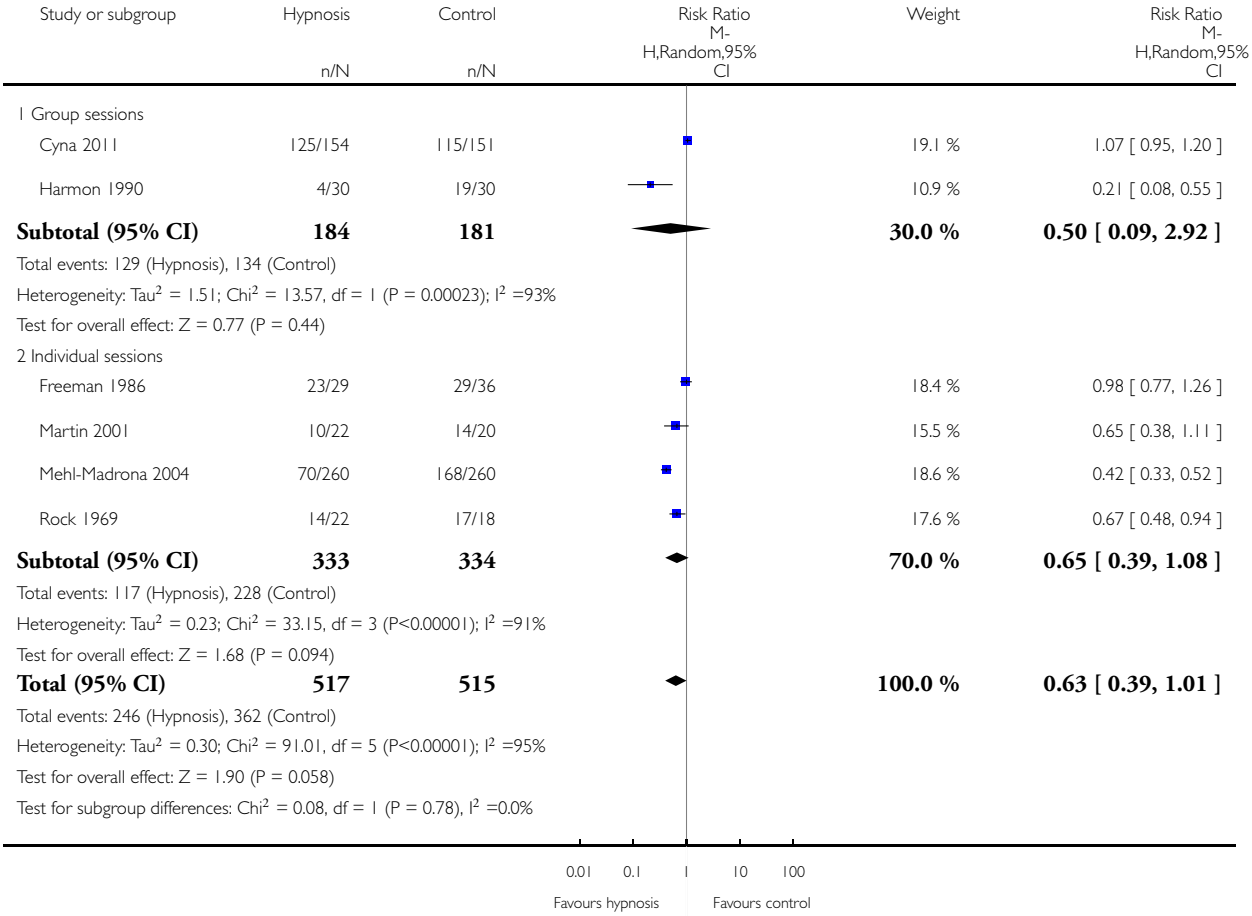
| Study or subgroup | Hypnosis n/N | Control n/N | Risk Ratio M-H,Random,95% CI | Weight | Risk Ratio M-H,Random,95% CI |
|---|---|---|---|---|---|
| 1 < 4 sessions | | | | | |
| Cyna 2011 | 85/154 | 92/151 | | 29.6 % | 0.91 [ 0.75, 1.10 ] |
| **Subtotal (95% CI)** | **154** | **151** | | **29.6 %** | **0.91 [ 0.75, 1.10 ]** |
| Total events: 85 (Hypnosis), 92 (Control) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 1.01 (P = 0.31) | | | | | |
| 2 4 or more sessions | | | | | |
| Freeman 1986 | 24/29 | 25/36 | | 27.4 % | 1.19 [ 0.91, 1.57 ] |
| Harmon 1990 | 24/30 | 15/30 | | 23.4 % | 1.60 [ 1.07, 2.39 ] |
| Martin 2001 | 22/22 | 8/20 | | 19.6 % | 2.42 [ 1.43, 4.07 ] |
| **Subtotal (95% CI)** | **81** | **86** | | **70.4 %** | **1.59 [ 1.06, 2.38 ]** |
| Total events: 70 (Hypnosis), 48 (Control) | | | | | |
| Heterogeneity: $Tau^2$ = 0.09; $Chi^2$ = 6.45, df = 2 (P = 0.04); $I^2$ =69% | | | | | |
| Test for overall effect: Z = 2.25 (P = 0.025) | | | | | |
| **Total (95% CI)** | **235** | **237** | | **100.0 %** | **1.35 [ 0.93, 1.96 ]** |
| Total events: 155 (Hypnosis), 140 (Control) | | | | | |
| Heterogeneity: $Tau^2$ = 0.11; $Chi^2$ = 16.31, df = 3 (P = 0.00098); $I^2$ =82% | | | | | |
| Test for overall effect: Z = 1.60 (P = 0.11) | | | | | |
| Test for subgroup differences: $Chi^2$ = 6.08, df = 1 (P = 0.01), $I^2$ =84% | | | | | |

## Analysis 5.1. Comparison 5 Individual sessions versus group sessions, Outcome 1 Use of pharmacological pain relief/anaesthesia.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 5 Individual sessions versus group sessions

Outcome: 1 Use of pharmacological pain relief/anaesthesia



### Analysis 5.2. Comparison 5 Individual sessions versus group sessions, Outcome 2 Spontaneous vaginal birth.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 5 Individual sessions versus group sessions

Outcome: 2 Spontaneous vaginal birth

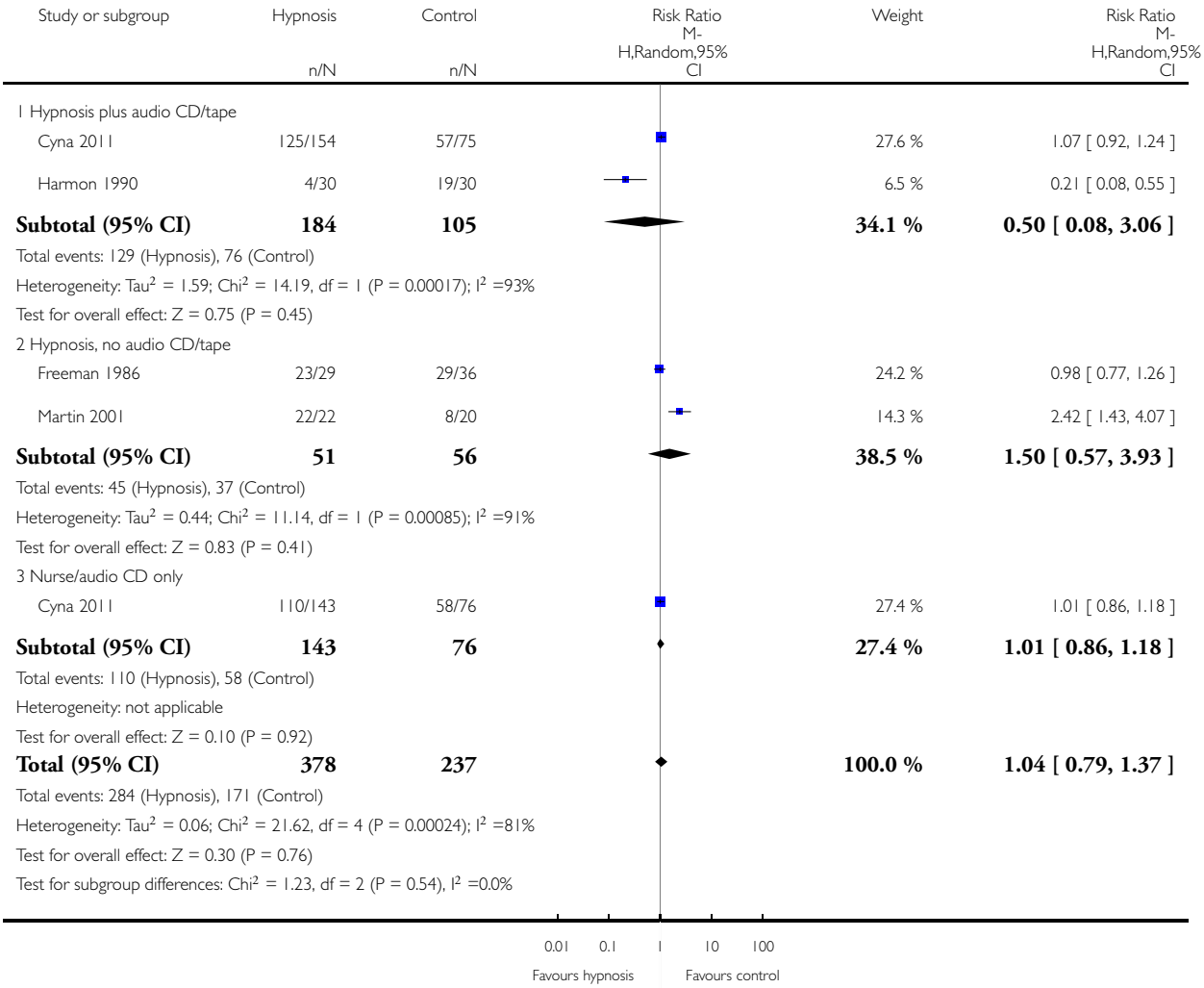
| Study or subgroup | Hypnosis n/N | Control n/N | Risk Ratio M-H,Random,95% CI | Weight | Risk Ratio M-H,Random,95% CI |
|---|---|---|---|---|---|
| 1 Group sessions | | | | | |
| Cyna 2011 | 85/154 | 92/151 | | 29.6 % | 0.91 [ 0.75, 1.10 ] |
| Harmon 1990 | 24/30 | 15/30 | | 23.4 % | 1.60 [ 1.07, 2.39 ] |
| **Subtotal (95% CI)** | **184** | **181** | | **53.0 %** | **1.17 [ 0.67, 2.04 ]** |
| Total events: 109 (Hypnosis), 107 (Control) | | | | | |
| Heterogeneity: $Tau^2 = 0.14$; $Chi^2 = 6.32$, df = 1 (P = 0.01); $I^2 = 84\%$ | | | | | |
| Test for overall effect: Z = 0.56 (P = 0.58) | | | | | |
| 2 Individual sessions | | | | | |
| Freeman 1986 | 24/29 | 25/36 | | 27.4 % | 1.19 [ 0.91, 1.57 ] |
| Martin 2001 | 22/22 | 8/20 | | 19.6 % | 2.42 [ 1.43, 4.07 ] |
| **Subtotal (95% CI)** | **51** | **56** | | **47.0 %** | **1.64 [ 0.79, 3.42 ]** |
| Total events: 46 (Hypnosis), 33 (Control) | | | | | |
| Heterogeneity: $Tau^2 = 0.24$; $Chi^2 = 6.25$, df = 1 (P = 0.01); $I^2 = 84\%$ | | | | | |
| Test for overall effect: Z = 1.33 (P = 0.18) | | | | | |
| **Total (95% CI)** | **235** | **237** | | **100.0 %** | **1.35 [ 0.93, 1.96 ]** |
| Total events: 155 (Hypnosis), 140 (Control) | | | | | |
| Heterogeneity: $Tau^2 = 0.11$; $Chi^2 = 16.31$, df = 3 (P = 0.00098); $I^2 = 82\%$ | | | | | |
| Test for overall effect: Z = 1.60 (P = 0.11) | | | | | |
| Test for subgroup differences: $Chi^2 = 0.52$, df = 1 (P = 0.47), $I^2 = 0.0\%$ | | | | | |

## Analysis 6.1. Comparison 6 Hypnosis plus audio CD/tape versus hypnosis no audio CD/tape versus nurse/audio CD only, Outcome 1 Use of pharmacological pain relief/anaesthesia.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 6 Hypnosis plus audio CD/tape versus hypnosis no audio CD/tape versus nurse/audio CD only

Outcome: 1 Use of pharmacological pain relief/anaesthesia



### Analysis 6.2. Comparison 6 Hypnosis plus audio CD/tape versus hypnosis no audio CD/tape versus nurse/audio CD only, Outcome 2 Spontaneous vaginal birth.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 6 Hypnosis plus audio CD/tape versus hypnosis no audio CD/tape versus nurse/audio CD only

Outcome: 2 Spontaneous vaginal birth

| Study or subgroup | Hypnosis n/N | Control n/N | Risk Ratio M-H,Random,95% CI | Weight | Risk Ratio M-H,Random,95% CI |
|---|---|---|---|---|---|
| 1 Hypnosis plus audio CD/tape | | | | | |
| Cyna 2011 | 85/154 | 46/75 | | 23.3 % | 0.90 [ 0.72, 1.13 ] |
| Harmon 1990 | 24/30 | 15/30 | | 17.5 % | 1.60 [ 1.07, 2.39 ] |
| **Subtotal (95% CI)** | **184** | **105** | | **40.9 %** | **1.17 [ 0.67, 2.05 ]** |
| Total events: 109 (Hypnosis), 61 (Control) | | | | | |
| Heterogeneity: $Tau^2$ = 0.14; $Chi^2$ = 5.98, df = 1 (P = 0.01); $I^2$ =83% | | | | | |
| Test for overall effect: Z = 0.55 (P = 0.58) | | | | | |
| 2 Hypnosis, no audio CD/tape | | | | | |
| Freeman 1986 | 24/29 | 25/36 | | 21.8 % | 1.19 [ 0.91, 1.57 ] |
| Martin 2001 | 22/22 | 8/20 | | 13.9 % | 2.42 [ 1.43, 4.07 ] |
| **Subtotal (95% CI)** | **51** | **56** | | **35.8 %** | **1.64 [ 0.79, 3.42 ]** |
| Total events: 46 (Hypnosis), 33 (Control) | | | | | |
| Heterogeneity: $Tau^2$ = 0.24; $Chi^2$ = 6.25, df = 1 (P = 0.01); $I^2$ =84% | | | | | |
| Test for overall effect: Z = 1.33 (P = 0.18) | | | | | |
| 3 Nurse/audio CD only | | | | | |
| Cyna 2011 | 84/143 | 46/76 | | 23.4 % | 0.97 [ 0.77, 1.22 ] |
| **Subtotal (95% CI)** | **143** | **76** | | **23.4 %** | **0.97 [ 0.77, 1.22 ]** |
| Total events: 84 (Hypnosis), 46 (Control) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 0.26 (P = 0.80) | | | | | |
| **Total (95% CI)** | **378** | **237** | | **100.0 %** | **1.24 [ 0.94, 1.63 ]** |
| Total events: 239 (Hypnosis), 140 (Control) | | | | | |
| Heterogeneity: $Tau^2$ = 0.07; $Chi^2$ = 16.54, df = 4 (P = 0.002); $I^2$ =76% | | | | | |
| Test for overall effect: Z = 1.51 (P = 0.13) | | | | | |
| Test for subgroup differences: $Chi^2$ = 2.02, df = 2 (P = 0.36), $I^2$ =1% | | | | | |

## Analysis 7.1. Comparison 7 Hypnosis preparation for labour versus hypnosis during labour, Outcome 1 Use of pharmacological pain relief/anaesthesia.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 7 Hypnosis preparation for labour versus hypnosis during labour

Outcome: 1 Use of pharmacological pain relief/anaesthesia

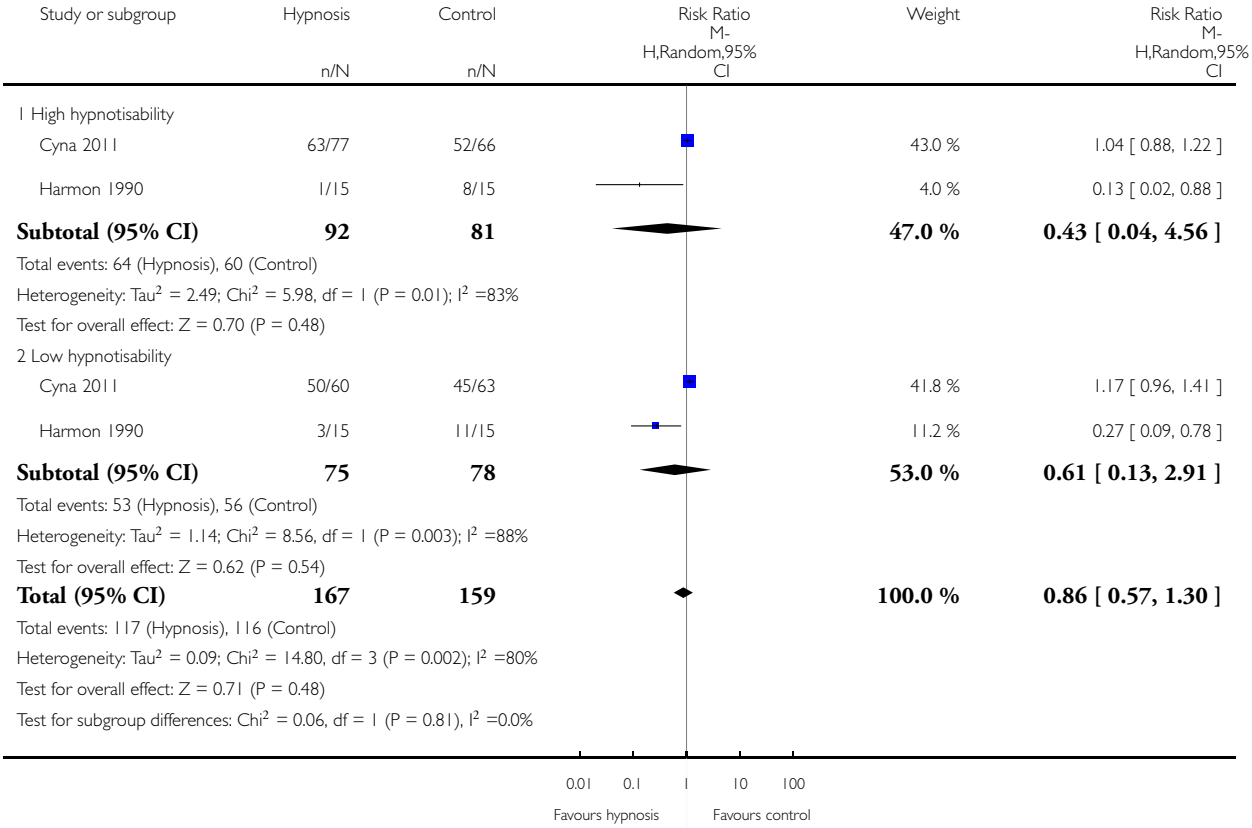
| Study or subgroup | Hypnosis n/N | Control n/N | Risk Ratio M-H,Random,95% CI | Weight | Risk Ratio M-H,Random,95% CI |
|---|---|---|---|---|---|
| 1 Hypnosis preparation for labour | | | | | |
| Cyna 2011 | 125/154 | 115/151 | | 19.1 % | 1.07 [ 0.95, 1.20 ] |
| Freeman 1986 | 23/29 | 29/36 | | 18.4 % | 0.98 [ 0.77, 1.26 ] |
| Harmon 1990 | 4/30 | 19/30 | | 10.9 % | 0.21 [ 0.08, 0.55 ] |
| Martin 2001 | 10/22 | 14/20 | | 15.5 % | 0.65 [ 0.38, 1.11 ] |
| Mehl-Madrona 2004 | 70/260 | 168/260 | | 18.6 % | 0.42 [ 0.33, 0.52 ] |
| **Subtotal (95% CI)** | **495** | **497** | | **82.4 %** | **0.62 [ 0.35, 1.09 ]** |
| Total events: 232 (Hypnosis), 345 (Control) | | | | | |
| Heterogeneity: $Tau^2$ = 0.36; $Chi^2$ = 90.95, df = 4 (P<0.00001); $I^2$ =96% | | | | | |
| Test for overall effect: Z = 1.67 (P = 0.095) | | | | | |
| 2 Hypnosis during labour | | | | | |
| Rock 1969 | 14/22 | 17/18 | | 17.6 % | 0.67 [ 0.48, 0.94 ] |
| **Subtotal (95% CI)** | **22** | **18** | | **17.6 %** | **0.67 [ 0.48, 0.94 ]** |
| Total events: 14 (Hypnosis), 17 (Control) | | | | | |
| Heterogeneity: not applicable | | | | | |
| Test for overall effect: Z = 2.31 (P = 0.021) | | | | | |
| **Total (95% CI)** | **517** | **515** | | **100.0 %** | **0.63 [ 0.39, 1.01 ]** |
| Total events: 246 (Hypnosis), 362 (Control) | | | | | |
| Heterogeneity: $Tau^2$ = 0.30; $Chi^2$ = 91.01, df = 5 (P<0.00001); $I^2$ =95% | | | | | |
| Test for overall effect: Z = 1.90 (P = 0.058) | | | | | |
| Test for subgroup differences: $Chi^2$ = 0.07, df = 1 (P = 0.79), $I^2$ =0.0% | | | | | |

## Analysis 8.1. Comparison 8 High hypnotisability versus low hypnotisability, Outcome 1 Use of pharmacological pain relief/anaesthesia.

Review: Hypnosis for pain management during labour and childbirth

Comparison: 8 High hypnotisability versus low hypnotisability

Outcome: 1 Use of pharmacological pain relief/anaesthesia

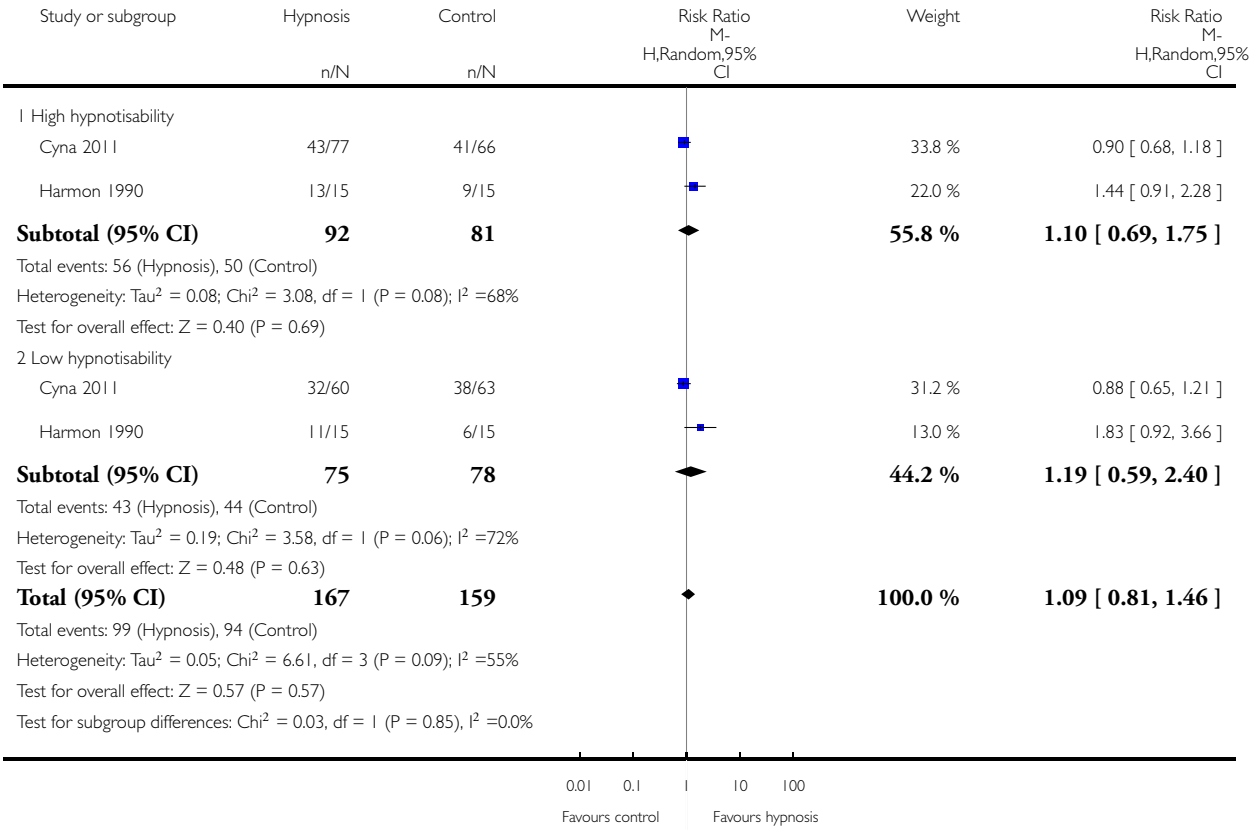


**Analysis 8.2. Comparison 8 High hypnotisability versus low hypnotisability, Outcome 2 Spontaneous vaginal birth.**

Review: Hypnosis for pain management during labour and childbirth

Comparison: 8 High hypnotisability versus low hypnotisability

Outcome: 2 Spontaneous vaginal birth




## HISTORY

Protocol first published: Issue 10, 2011

Review first published: Issue 11, 2012

## CONTRIBUTIONS OF AUTHORS

K Madden: contributed to writing the manuscript.

AM Cyna: conceived the review topic, contributed to writing the draft manuscript.

P Middleton: reviewed the entire protocol, adapted part of the methods and provided advice on statistical analysis and methodology.

M Matthewson: commented on drafts.

L Jones: screened papers for eligibility; checked all quality appraisal, data extraction and data entry; wrote to authors of papers for additional information; entered data into RevMan; carried out data analysis; wrote first draft of description of studies and effects of interventions sections; reviewed final draft of review.

## DECLARATIONS OF INTEREST

K Madden used hypnosis during the births of her two children and teaches private childbirth education classes, which include psychological strategies for comfort.

AM Cyna recently completed the Hypnosis Antenatal Training for Childbirth (HATCh) RCT which is included in this review. None of the study assessors were involved in the HATCh trials but AM Cyna was K Madden's secondary supervisor for honours and is the secondary supervisor for a masters thesis which will be based on this Cochrane Review. M Matthewson is the primary supervisor for the masters thesis but had no involvement with the HATCh trial.

## SOURCES OF SUPPORT


### Internal sources

- No sources of support supplied

### External sources

- Nursing and Allied Health Scholarship and Support Scheme (NAHSSS), Australia.

K Madden has been supported by a scholarship from the NAHSSS funded by the Department of Health and Ageing. The views expressed in this review do not necessarily represent those of the NAHSSS, its Administrator, Services for Australian Rural and Remote Allied Health (SARRAH) and/or the Australian Government Department of Health and Ageing.

- National Institute for Health Research, UK.

Cochrane-NHS Engagement Project No: 10/4000/02

The above project supported Leanne Jones's involvement as author


## DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The protocol stated that we would exclude quasi-randomised trials. We revised this decision to include quasi-randomised controlled trials due to the small number of trials available for inclusion. This decision also ensured that the current review is consistent with the inclusion criteria used for the earlier review of complementary and alternative therapies for pain management in labour which included hypnosis (Smith 2006).

The planned subgroup comparisons for trimester (first versus second versus third trimester; first and second trimester versus third trimester) at commencement of hypnosis was revised to; first and second trimester versus second trimester versus third trimester as all trials could be included in this format within the one comparison.

The planned subgroup comparison for method of hypnosis intervention delivery (audio CD versus no audio CD) was revised to; hypnosis plus audio CD versus hypnosis no audio CD versus nurse/audio CD only to include data from all groups where audio CDs were used.

## INDEX TERMS

### Medical Subject Headings (MeSH)

Analgesia, Obstetrical [*methods]; Hypnosis [*methods]; Labor Pain [psychology; *therapy]; Labor, Obstetric [psychology]; Length of Stay; Patient Satisfaction; Randomized Controlled Trials as Topic; Time Factors

### MeSH check words

Female; Humans; Pregnancy